Technical Alert

# Update to the Permissible Ingredients Determination (No. 1 of 2021)

A new Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2021, has been approved by the delegate to the Secretary and entered onto the Federal Register of Legislation here. This instrument is made under section 26BB of the Therapeutic *Goods Act 1989* ('the Act') and repeals the *Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020*.

This Technical Alert contains a list of changes with a Checklist/Notes field for sponsors to use to assist in identifying the changes, as part of a table which includes:

- Each new or changed ingredient
- The original requirements
- New (amended) specific requirements.

If members identify concerns or errors with the changes to the Determination, please contact CMA at technical@cmaustralia.org.au

For ingredients that have changed:

**Sponsors** should review affected products for changes to compliance requirements (this may include increased or decreased regulatory requirements).

**Suppliers of proprietary ingredients** should also ensure that changes are checked and up to date and provide relevant information to sponsors of products. Sponsors are responsible for compliance of their products under the Act and should check with proprietary ingredient suppliers.

## Notable changes to existing ingredients in the Determination

**Update to applicable requirements:**

- **Inorganic magnesium salts**: Following the August 2020 consultation on Low-negligible risk changes to Permissible Ingredients - 2020-2021, requirements for 19 inorganic magnesium salts have been amended to reflect an identified risk of laxative effects at high doses associated with these ingredients. This means that many medicines with the following ingredients are likely to require a new warning statement to be implemented immediately on new products, or over the next 12 months for existing products, subject to the dose-dependent levels outlined in the Determination These include:
    - ALUMINIUM MAGNESIUM SILICATE
    - BITTERN
    - DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE
    - DRIED MAGNESIUM SULFATE
    - HEAVY MAGNESIUM OXIDE
    - LIGHT MAGNESIUM OXIDE
    - MAGNESIUM AMINO ACID CHELATE
    - MAGNESIUM CHLORIDE 4.5-HYDRATE
    - MAGNESIUM CHLORIDE HEXAHYDRATE
    - MAGNESIUM HYDROGEN PHOSPHATE

- MAGNESIUM HYDROXIDE
- MAGNESIUM OXIDE
- MAGNESIUM PHOSPHATE PENTAHYDRATE
- MAGNESIUM PHOSPHATE TRIBASIC
- MAGNESIUM SULFATE DIHYDRATE
- MAGNESIUM SULFATE HEPTAHYDRATE
- MAGNESIUM SULFATE MONOHYDRATE
- MAGNESIUM SULFATE TRIHYDRATE
- MAGNESIUM TRISILICATE

More background information can be found in CMA's 2 December 2020 technical alert.

- ***Andrographis paniculata**:* Following reports of loss of taste or taste disturbance associated with listed medicines containing Andrographis, the TGA considers that the available evidence establishes a risk of loss of taste or taste disturbance from any listed medicine containing Andrographis and believes that the risk should be communicated at the time of purchase to ensure consumers can associate adverse events with the product, should they occur. As a result, requirements for *Andrographis paniculata* have been amended to reflect an identified risk of taste disturbance associated with this ingredient. More information in CMA's 2 December 2020 technical alert;
- **Caffeine:** following an application that was made to the Secretary for a variation to allow for its use as an active ingredient for topical administration, the requirements for caffeine have been amended to include topical medicines for dermal application that are directed for use in adults only.

**Removal of ingredients**

- Following a targeted industry consultation via CMA in December 2020, *Gynura japonica* has been removed, as this ingredient contains hepatotoxic pyrrolizidine alkaloids. More information available via CMA's 16 December technical alert;
- psoralen (of *Cullen corylifolium*), as this entry refers to a component of the existing ingredient '*Cullen corylifolium*' and was incorrectly included as an ingredient in the initial Determination; and
- chloroacetamide, as this ingredient is a contact allergen specified in a Schedule to the Poisons Standard.

### Summary of all changes to the Determination

A number of changes have been made in the Determination. The changes include:

- the addition of the following four new ingredients for use in listed and assessed listed medicines:
  - 2'-fucosyllactose;
  - fully hydrogenated rapeseed oil;
  - C15-16 isoparaffin; and
  - C17-18 isoparaffin;
- the addition of the ingredient 3-(methylthio) propionaldehyde for use in flavour proprietary excipient formulations in listed and assessed listed medicines;

- updating the ingredient name *Ledum groenlandicum* to the currently taxonomically accepted name *Rhododendron groenlandicum*;
- updates to applicable requirements for the following ingredients:
    - 19 inorganic magnesium salts, to reflect an identified risk of laxative effects at high doses associated with these ingredients;
    - *Andrographis paniculata,* to reflect an identified risk of taste disturbance associated with this ingredient;
    - caffeine, to allow for its use as an active ingredient for topical administration following an application that was made to the Secretary for this variation; and
    - formic acid and para-propyl anisole, to reflect evaluations for their use in flavour proprietary excipient formulations;
- minor clarifications, and correction of minor typographical errors for the purpose of improving the internal consistency of the Determination, including the following changes:
    - the specification of product warning codes for existing warning statements required in 4 ingredients, which were inadvertently omitted in previous determinations made under section 26BB of the Act;
    - clarification of requirements for *Conium maculatum* relating to homoeopathic potency;
    - clarification of requirements for cis-3-hexen-1-ol relating to the concentration of flavour proprietary excipient ingredients;
    - the removal of requirements relating to folic acid which are specified in the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021, and had been incorrectly included for 3 other ingredients; and
    - a correction of an error in relation to a requirement for sodium propionate that had been incorrectly applied in the initial Determination.
- the removal of duplicative requirements for 125 ingredients, to reflect that the applicable requirements separately apply to medicines that may contain the ingredients under *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* ("TGO 92"); and
- the removal of the following three ingredients which are not appropriate for inclusion in listed or assessed listed medicines:
    - *Gynura japonica*, as this ingredient contains hepatotoxic pyrrolizidine alkaloids;
    - psoralen (of *Cullen corylifolium*), as this entry refers to a component of the existing ingredient '*Cullen corylifolium*' and was incorrectly included as an ingredient in the initial Determination; and
    - chloroacetamide, as this ingredient is a contact allergen specified in a Schedule to the Poisons Standard.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| 2'-fucosyllactose | Addition | | A | | Only to be used in a medicine where BASF Australia Ltd - Australia (Client ID 13479), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2023.<br><br>Only for oral use.<br><br>The maximum recommended daily dose of the medicine must not provide more than:<br><br>(a) 5 g of 2'-fucosyllactose to individuals aged 18 years and older;<br><br>(b) 2 g of 2'-fucosyllactose to individuals aged between 4 to 17 years (inclusive); and | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (c) 1.2 g of 2'-fucosyllactose to individuals aged between 1 to 3 years (inclusive).<br><br>Not permitted for use in children under the age of 12 months. | |
| 3-(methylthio) propionaldehyde | Addition | | E | | 3-(Methylthio) propionaldehyde must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total concentration of flavour proprietary excipient formulations containing 3-(methylthio) propionaldehyde must not be more than 5% of the total medicine. | |
| acetyl glucosamine | Change | E | E | ~~Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.~~ | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. | |

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| | | | | ~~If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SFOOD) 'Derived from seafood'~~ | | |
| alginate-konjac-xanthan polysaccharide complex | Change | A | A | ~~Only for use in oral medicines.~~<br>~~Only for use when the dosage form is other than tablet.~~<br>~~The maximum recommended daily dose must be no more than 13.5 g.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~<br>~~When a dose for children is stated, the medicine requires the following warning~~ | Only for use in oral medicines.<br>Only for use when the dosage form is other than tablet.<br>The maximum recommended daily dose must be no more than 13.5 g.<br>When a dose for children is stated, the medicine requires the following warning statement on the medicine label:<br>- (PSYLL) 'On medical advice' (or words to that effect). | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~statement on the medicine label:~~<br>~~- (PSYLL) 'On medical advice' (or words to that effect).~~ | | |
| alpha casozepine enriched hydrolysed milk protein | Change | A | A | ~~Only for use in oral medicines. The medicine requires the following warning statements on the medicine label:~~<br>~~- (BABY3) 'Not suitable for use in children under the age of twelve months - except on professional advice'~~<br>~~- (COWMK) 'Derived from cow's milk.'~~ | Only for use in oral medicines. The following warning statement is required on the medicine label:<br>- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect). | |
| aluminium magnesium silicate | Change | E | E | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of aluminium magnesium silicate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A ) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| aluminium sodium silicate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| Amylase | Change | A | A | ~~Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline. When used in a divided preparation, the allowed unit is Alpha-amylase dextrinising unit or Thousand alpha-amylase dextrinising unit. When used as an undivided preparation, the allowed unit is Thousand alpha-amylase dextrinising unit per gram or Dextrinising unit per gram.~~ | Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | | |
| Andrographis paniculata | Change | A, H | A, H | ~~The following warning statement is required on the label:~~<br>~~- (ANDROG) 'Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis) stop use and seek immediate medical attention' (or words to that effect).~~ | The following warning statement is required on the label:<br>- (ANDROG) 'Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention' (or words to that effect).<br>The requirement specified in paragraph (a) below applies to medicines that contain the ingredient that are:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) When for oral use, the following warning statement is required on the medicine label:<br>- (ANDROT) 'Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical | |

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| | | | | | advice' (or words to that effect). | |
| Arachis hypogaea | Change | A, E, H | A, E, H | ~~The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).~~ | | |
| Arachis Oil | Change | A, E, H | A, E, H | ~~The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).~~ | | |
| aspartame | Change | E | E | ~~When for oral use, the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this product contains phenylalanine (or words to that effect)' The medicine requires the following warning statement on the medicine label: - (ASPAR) 'Contains aspartame'~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| benzyl benzoate | Change | E | E | ~~Only for use in topical medicines for dermal application. Medicines containing benzoates require the warning statement: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.~~ | Only for use in topical medicines for dermal application. | |
| bittern | Change | A, E, H | A, E, H | ~~Only to be used in a medicine where WA Salt Koolyanobbing Pty Ltd- Australia (Client ID 69736), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 8 June~~ | Only to be used in a medicine where WA Salt Koolyanobbing Pty Ltd- Australia (Client ID 69736), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 8 June | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~2022.~~<br>~~Magnesium is a mandatory component of bittern.~~<br>~~Only permitted for use in:~~<br>~~- medicines limited to oral routes of administration; and~~<br>~~- topical medicines for dermal administration.~~<br>~~When the medicine is:~~<br>~~(a) used in medicines with an oral route of administration;~~<br>~~(b) not promoted or marketed as laxative; and~~<br>~~(c) the recommended daily dose for:~~<br>~~(i) individuals greater than 9 years of age contains 250 mg or greater magnesium;~~<br>~~(ii) children aged between 4 and 8 years (inclusive) contains 110 mg or greater magnesium; or~~<br>~~(iii) children aged between 1 and 3 years (inclusive) contains 65 mg or greater magnesium;~~<br>~~the following warning statements are required on the label:~~<br>~~- (LAX5) 'This product contains~~ | 2022.<br>Magnesium is a mandatory component of bittern.<br>Only permitted for use in:<br>- medicines limited to oral routes of administration; and<br>- topical medicines for dermal administration.<br>When used in a medicine:<br>(a) with an oral route of administration;<br>(b) not indicated for laxative (or related) use; and<br>(c) where the maximum recommended daily dose for:<br>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning | |

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| | | | | ~~magnesium'; and~~<br>~~- (LAX4) 'This product may have laxative effect'.~~<br>~~When the medicine is for an oral route of administration, the following warning statement is required on the label:~~<br>~~- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).~~ | statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| blackstrap molasses | Change | E | E | ~~When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert~~ | When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap. | |

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| | | | | ~~name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| bovine colostrum powder | Change | A | A | ~~The medicine requires the warning statement: - (BOVCOL) 'Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'~~ | The following warning statement is required on the medicine label:<br>- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect). | |
| bovine lactoferrin | Change | A | A | ~~The medicine requires the following warning statement on the medicine label:~~ | | |

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| | | | | ~~- (COWMK) 'Derived from cow's milk.'~~ | | |
| Bovine whey Ig-rich fraction | Change | A | A | ~~Only for use in oral medicines. The medicine requires the following warning statements on the medicine label:~~<br>~~- (COWMK) 'Derived from cows milk'~~<br>~~- (BABY3) 'Not suitable for use in children under the age of 12 months - except on the advice of a health professional)'.~~ | Only for use in oral medicines. The following warning statement is required on the medicine label:<br>- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect). | |
| bromelains | Change | A | A | ~~May be derived from either the stem or fruit of the pineapple (Ananas comosus). If used in a divided preparation, the allowed units are papain units and million papain units.~~<br>~~If used in an undivided preparation, the allowed units are million papain units per gram.~~ | May be derived from either the stem or fruit of the pineapple (Ananas comosus). | |

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| butyl hydroxybenzoate | Change | E | E | ~~Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | Only for use in topical medicines for dermal application. | |
| C15-16 isoparaffin | Addition | | E | | C15-16 isoparaffin must only be included in topical medicines:<br>(a) for dermal application; and<br>(b) where the dosage form of the medicine is not spray.<br>The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.<br>When the nominal capacity of the container is more than 2 mL | |

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| | | | | | and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%. | |
| C17-18 isoparaffin | Addition | | E | | C17-18 isoparaffin must only be included in topical medicines:<br>(a) for dermal application; and<br>(b) where the dosage form of the medicine is not spray.<br>The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.<br>When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C17-18 isoparaffin) in the medicine must not be more than 25%. | |
| caffeine | Change | A, E | A, E | ~~When used as an excipient, only for use in topical~~ | When used as an excipient, only for use in topical medicines for | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~medicines for dermal application.~~<br>~~Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine).~~<br>~~When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg of caffeine from this ingredient.~~<br>~~When for internal use or oral application, the following warning statement is required on the medicine label:~~<br>~~- (ADULT) 'Adults only' (or words to that effect).~~<br>~~When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine~~ | dermal application.<br>Only for use as an active ingredient for:<br>(a) oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and<br>(b) topical medicines for dermal application that are directed for use in adults only.<br>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg of caffeine from this ingredient.<br>When for internal use or oral application, the following warning statement is required on the medicine label:<br>- (ADULT) 'Adults only' (or words to that effect).<br>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~greater than 4%.~~<br>~~When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.~~<br>~~The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:~~<br>~~- is listed in the Register on or after 2 September 2019; or~~<br>~~- is supplied after 2 March 2021.~~<br>~~A medicine that contains the ingredient and that:~~<br>~~- was listed in the Register before 2 September 2019; and~~<br>~~- is supplied before 2 March 2021;~~<br>~~may comply with the requirements in paragraphs (a) to (d) below.~~<br>~~a) When the medicine is packaged for supply as an undivided preparation and is~~ | greater than 4%.<br>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.<br>When for topical application:<br>(a) the concentration of total caffeine in the medicine must not be more than 1%; and<br>(b) the medicine must not be intended for use on broken skin.<br><br>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:<br>- is listed in the Register on or after 2 September 2019; or<br>- is released for supply after 2 March 2021.<br>A medicine that contains the ingredient and that:<br>- was listed in the Register before 2 September 2019; and<br>- is released for supply before 2 | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.~~<br>~~b) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.~~<br>~~c) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:~~<br>~~- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'~~ | March 2021;<br>may comply with the requirements in paragraphs (a) to (d) below.<br>(a) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.<br>(b) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.<br>(c) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:<br>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit | |

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| | | | | ~~- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'~~<br>~~d) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:~~<br>~~- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'~~<br>~~- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).~~ | or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'<br>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'<br>(d) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:<br>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'<br>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). | |
| calcium folinate | Change | A | A | ~~Folinic acid is a mandatory component of calcium folinate.~~ | Folinic acid is a mandatory component of calcium folinate. The maximum recommended | |

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| | | | | ~~The maximum daily dose must not provide more than 500 micrograms of folinic acid.~~<br>~~When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.~~<br>~~When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following warning statement is required on the medicine label:~~<br>~~- (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect).~~ | daily dose must not provide more than 500 micrograms of folinic acid.<br>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| calcium sodium caseinate | Change | A, H | A, H | ~~The medicine requires the following warning statement on the medicine label:~~<br>~~- (COWMK) 'Derived from cow's milk'.~~ | | |
| Canarium indicum | Change | A, H | A, H | ~~The plant part must be seed and the plant preparation is oil.~~<br>~~The medicine requires the following warning statement on the medicine label:~~<br>~~- (DERIVED) 'This product contains material derived from nuts' (or words to that effect).~~ | Only for use when the plant part is seed and the plant preparation is oil. | |
| cellulase | Change | A | A | ~~Must be derived from Trichoderma longibrachiatum only.~~<br>~~If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram.~~<br>~~If used as an divided preparation, the allowed unit~~ | Must be derived from Trichoderma longibrachiatum only. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~is Thousand cellulase unit or cellulase unit.~~ | | |
| Change of name from Ledum groenlandicum to Rhododendron groenlandicum | Change | A, H | A, H | | | |
| chloroacetamide | Removal | E | | ~~Only for use in topical medicines for dermal application.~~ | | |
| cis-3-hexen-1-ol | Change | E | E | ~~Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.~~ ~~Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.~~ ~~If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.~~ | cis-3-Hexen-1-ol must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation.<br>The total concentration of flavour proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 5% of the total medicine.<br>The total concentration of fragrance proprietary excipient formulations containing cis-3- | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | hexen-1-ol must not be more than 1% of the total medicine. | |
| Conium maculatum | Change | H | H | ~~Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.~~ | Only for use as an active homoeopathic ingredient.<br>The homoeopathic potency of Conium maculatum in the final medicine must be 12X or greater. | |
| croscarmellose sodium | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:<br>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| dibasic magnesium phosphate trihydrate | Change | A, E, H | A, E, H | ~~Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.~~<br>~~The percentage of magnesium~~ | Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.<br>The percentage of magnesium | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.~~ | from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.<br>The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| dibasic sodium phosphate | Change | A, E, H | A, E, H | ~~When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.~~<br>~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a~~ | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~semi-solid preparation, the pH of the preparation must not exceed 11.5.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | preparation must not exceed 11.5. | |
| dibasic sodium phosphate dihydrate | Change | A, E, H | A, E, H | ~~When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.~~<br>~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH~~ | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~of the preparation must not exceed 11.5.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | preparation must not exceed 11.5. | |
| dibasic sodium phosphate dodecahydrate | Change | A, E, H | A, E, H | ~~When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate.~~<br>~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not~~ | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~exceed 11.5.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | preparation must not exceed 11.5. | |
| dibasic sodium phosphate heptahydrate | Change | A, E, H | A, E, H | ~~When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate.~~<br>~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.~~ | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | preparation must not exceed 11.5. | |
| dibasic sodium phosphate monohydrate | Change | A, E, H | A, E, H | ~~When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate.~~ ~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~ ~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.~~ ~~When for oral or sublingual~~ | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| disodium edetate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| dried magnesium sulfate | Change | A, E, H | A, E, H | ~~When used internally, the maximum recommended~~ | When used internally, the maximum recommended daily | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~daily dose must be no more than 1.5g.~~ | dose must be no more than 1.5g.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of dried magnesium sulfate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| ethanol absolute | Change | A, E | A, E | ~~When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of~~ | When ethanol absolute is used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'~~ | | |
| ethyl hydroxybenzoate | Change | E | E | ~~Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | | |
| euphausia superba oil | Change | A | A | ~~Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'~~ | Only for use in oral medicines. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~or~~<br>~~- (SHELL) 'Contains crustacean shellfish'.~~ | | |
| folic acid | Change | A | A | ~~When for internal use, the maximum recommended daily dose must be no more than 500 micrograms of folic acid.~~<br>~~When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.~~<br>~~When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects:~~<br>~~a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and~~<br>~~b) the following statement must be included on the label:~~<br>~~- (NEUR) 'Warning: Do not exceed the stated dose except~~ | When for internal use, the maximum recommended daily dose must not provide more than 500 micrograms of folic acid.<br>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.~~ | | |
| formic acid | Change | H | E, H | ~~Only for use as an active homoeopathic ingredient.~~ | Formic acid must only be included in medicines:<br>(a) as an active homoeopathic ingredient; or<br>(b) when in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total concentration of flavour proprietary excipient formulations containing formic acid must not be more than 5% of the total medicine.<br>The maximum recommended daily dose of the medicine must not provide more than 150 mg of formic acid.<br>The total concentration of formic acid in the medicine must not be more than 0.5%. | |
| fortified wine | Change | E | E | ~~Ethanol is a mandatory component of fortified wine.~~ | Ethanol is a mandatory component of fortified wine. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:~~<br>~~- (ETHAN) 'Contains ethanol or contains alcohol'.~~ | | |
| fully hydrogenated rapeseed oil | Addition | | E | - | Fully hydrogenated rapeseed oil must only be used in topical medicines for dermal application.<br>The total concentration of fully hydrogenated rapeseed oil in the medicine must not be more than 5%. | |
| glucosamine hydrochloride | Change | A, E | A, E | ~~When derived from seafood, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SFOOD) 'Derived from seafood'.~~ | | |
| glucosamine sulfate | Change | A | A | ~~When derived from seafood, the medicine requires the following warning statement on the medicine label:~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~- (SFOOD) 'Derived from seafood'.~~ | | |
| glucosamine sulfate potassium chloride | Change | A | A | ~~Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride.~~<br>~~When derived from seafood, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SFOOD) 'Derived from seafood'.~~<br>~~When for oral use, the medicine requires the following warning statement on the medicine label:~~<br>~~- (POTAS) 'Contains [amount of potassium in milligrams] mg of potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'~~ | Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.' | |
| glucosamine sulfate sodium chloride | Change | A | A | ~~When derived from seafood, the medicine requires the~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~following warning statement on the medicine label:~~<br>~~- (SFOOD) 'Derived from seafood'.~~ | | |
| glucose | Change | A, E, H | A, E, H | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| glucose monohydrate | Change | A, E, H | A, E, H | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose monohydrate, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| goat milk | Change | E | E | ~~If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| golden syrup | Change | E | E | ~~Sucrose is a mandatory component of Golden syrup when the route of administration of the medicine is oral or sublingual. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR~~ | When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| grape wine red | Change | E | E | ~~Ethanol is a mandatory component of Grape wine red.~~<br>~~When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:~~<br>~~- (ETHAN) 'Contains ethanol' or 'contains alcohol'~~ | Ethanol is a mandatory component of grape wine red. | |
| grape wine sherry | Change | E | E | ~~Ethanol is a mandatory component of Grape wine sherry.~~<br>~~When the concentration of ethanol in the medicine is more than 3%, the medicine~~ | Ethanol is a mandatory component of grape wine sherry. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'~~ | | |
| grape wine white | Change | E | E | ~~Ethanol is a mandatory component of Grape wine white. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'~~ | Ethanol is a mandatory component of grape wine white. | |
| Gynura japonica | Removal | A, H | | | | |
| heavy magnesium oxide | Change | A, E, H | A, E, H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of heavy | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | magnesium oxide.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| Honey | Change | A, E | A, E | ~~When the route of administration is oral, the medicine requires the following warning statement on the medicine label:~~<br>~~- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR~~<br>~~'Contains sugars' (or words to~~ | When the route of administration is oral, the following warning statement is required on the medicine label:<br>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| honey extract | Change | E | E | ~~Not to be included in medicines intended for use in the eye.~~<br>~~The concentration in the medicine must be no more than 1%.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine~~ | Honey extract must not be included in medicines intended for use in the eye.<br>The concentration of honey extract in the medicine must not be more than 1%. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~ | | |
| invert sugar | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| invert syrup | Change | E | E | ~~Glucose is a mandatory component of Invert syrup when the route of administration is oral or sublingual.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the~~ | When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| isobutyl hydroxybenzoate | Change | E | E | ~~Only for use in topical medicines for dermal application.~~<br>~~Medicines containing hydroxybenzoates require the following warning statement on the medicine label:~~<br>~~- (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | Only for use in topical medicines for dermal application. | |
| isomalt | Change | E | E | ~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.~~ | | |
| isopropyl 4-hydroxybenzoate | Change | E | E | ~~Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | Only for use in topical medicines for dermal application. | |
| lactitol | Change | E | E | ~~The medicine requires the following warning statements~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on the medicine label:~~<br>~~- (SUGOLS) 'Medicines containing lactitol may have a laxative effect or cause diarrhoea' (or words to that effect);~~<br>~~- (LACT) 'Contains lactose' (or words to that effect); and~~<br>~~- (COWMK) 'Derived from cows milk'.~~ | | |
| lactitol monohydrate | Change | E | E | ~~The medicine requires the following warning statements on the medicine label:~~<br>~~- (SUGOLS) 'Medicines containing lactitol monohydrate may have a laxative effect or cause diarrhoea' (or words to that effect)~~<br>~~- (LACT) 'Contains lactose' (or words to that effect)~~<br>~~- (COWMK) 'Derived from cows milk'.~~ | | |
| lactose | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars [or words to that effect]' if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose [or words to that effect]'.~~ | | |
| lactose monohydrate | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose monohydrate, maltose, and sucrose) is more than 100mg~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR~~<br>~~'Contains sugars [or words to that effect]' if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose monohydrate then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose monohydrate [or words to that effect]'.~~ | | |
| levomefolate calcium | Change | A | A | ~~Available for medicines intended for internal use only.~~<br>~~Levomefolic acid is a mandatory component of Levomefolate calcium.~~<br>~~The maximum recommended daily dose must not provide more than 500 micrograms of Levomefolic acid from Levomefolate calcium.~~ | Available for medicines intended for internal use only.<br>Levomefolic acid is a mandatory component of levomefolate calcium.<br>The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate calcium. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects the following warning statement is required on the medicine label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.~~ | When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. | |
| levomefolate glucosamine | Change | A | A | ~~Available for medicines intended for internal use only. Levomefolic acid is a~~ | Available for medicines intended for internal use only. Levomefolic acid is a mandatory | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~mandatory component of levomefolate glucosamine.~~<br>~~The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine.~~<br>~~When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.~~<br>~~When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects the following warning statement is required on the medicine label:~~<br>~~- (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek~~ | component of levomefolate glucosamine.<br>The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine.<br>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~specific medical advice (or words to that effect).'~~ | | |
| light magnesium oxide | Change | A, E, H | A, E, H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022. (a) Magnesium is a mandatory component of light magnesium oxide.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| lipase | Change | A | A | ~~Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline.~~<br>~~When used in an undivided preparation, the unit 'Thousand lipase units per gram' is permitted.~~<br>~~When used in a divided preparation, the unit~~ | Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~'Thousand lipase unit' is permitted.~~ | | |
| liquid glucose | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR~~<br>~~'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| magnesium amino acid chelate | Change | A, E, H | A, E, H | ~~Only for use in oral medicines. The concentration of Magnesium must be no more than 25% of the magnesium amino acid chelate.~~ | Only for use in oral medicines.<br>The concentration of magnesium must be no more than 25% of the magnesium amino acid chelate.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium amino acid chelate.<br>(b) When used in a medicine:<br>(i) not indicated for laxative (or related) use; and<br>(ii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium chloride 4.5-hydrate | Change | A | A | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium chloride 4.5-hydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| magnesium chloride hexahydrate | Change | A, E, H | A, E, H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium chloride hexahydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium hydrogen phosphate | Change | H | H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium hydrogen phosphate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| magnesium hydroxide | Change | A, E | A, E | ~~When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.~~ ~~When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose, the following warning statements are required on the label:~~ ~~- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'~~ ~~- (LAX4) 'This product may have laxative effect'.~~ | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.<br>The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register before 1 March 2021;<br>- released for supply before or on 1 March 2022; and<br>- the following warning statement is not specified on the label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(a) When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose, the following warning | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | statements are required on the label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'<br>- (LAX4) 'This product may have laxative effect'.<br>The requirements specified in paragraphs (b) to (d) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(b) Magnesium is a mandatory component of magnesium hydroxide.<br>(c) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(d) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium oxide | Change | A, E, H | A, E, H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | (a) Magnesium is a mandatory component of magnesium oxide.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium phosphate pentahydrate | Change | A, E, H | A, E, H | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium phosphate pentahydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium phosphate tribasic | Change | A, E, H | A, E, H | ~~Magnesium is a mandatory component of Magnesium phosphate tribasic.~~<br>~~The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular~~ | Magnesium is a mandatory component of magnesium phosphate tribasic.<br>The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~weight of magnesium phosphate tribasic.~~ | tribasic.<br>The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium sulfate dihydrate | Change | A, E, H | A, E, H | ~~When used internally, the maximum recommended daily dose must be no more than 1.5g.~~ | When used internally, the maximum recommended daily dose must not be more than 1.5g.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium sulfate dihydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | for use in infants younger than 12 months of age. | |
| magnesium sulfate heptahydrate | Change | A, E, H | A, E, H | ~~When used internally, the maximum recommended daily dose must be no more than 1.5g.~~ | When used internally, the maximum recommended daily dose must not be more than 1.5 g.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium sulfate heptahydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium sulfate monohydrate | Change | A, E, H | A, E, H | ~~When used internally, the maximum recommended daily dose must be no more than 1.5g.~~ | When used internally, the maximum recommended daily dose must not be more than 1.5 g.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | - listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium sulfate monohydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| magnesium sulfate trihydrate | Change | A, E, H | A, E, H | ~~When used internally, the maximum recommended daily dose must be no more than 1.5g.~~ | When used internally, the maximum recommended daily dose must not be more than 1.5 g.<br>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium sulfate trihydrate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| magnesium trisilicate | Change | E | E | | The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:<br>- listed in the Register on or after 1 March 2021; or<br>- released for supply after 1 March 2022.<br>(a) Magnesium is a mandatory component of magnesium trisilicate.<br>(b) When used in a medicine:<br>(i) with an oral route of administration;<br>(ii) not indicated for laxative (or related) use; and<br>(iii) where the maximum recommended daily dose for:<br>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;<br>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or<br>(C) individuals aged 9 years or older provides 350 mg or more | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | | total magnesium from inorganic magnesium salts;<br>the following warning statement is required on the medicine label:<br>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).<br>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age. | |
| maltitol | Change | E | E | ~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:<br>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~diarrhoea [or words to that effect]'.~~ | | |
| maltitol solution | Change | E | E | ~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).~~ | | |
| maltose | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| mannitol | Change | E | E | ~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~diarrhoea' (or words to that effect).~~ | | |
| methyl hydroxybenzoate | Change | E | E | ~~Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | | |
| monobasic sodium phosphate | Change | A, E, H | A, E, H | ~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in~~ | When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| monobasic sodium phosphate dihydrate | Change | E | E | ~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state~~ | When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~quantity and units] of sodium' (or words to that effect).~~ | | |
| monosodium dihydrogen citrate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| nicotinamide riboside chloride | Change | A | A | ~~Only to be used in a medicine where Chromadex Inc (Client ID 68566), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this~~ | Only to be used in a medicine where Chromadex Inc (Client ID 68566), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~ingredient after 02 December 2021.~~<br>~~Ribose is a mandatory component of Nicotinamide riboside chloride.~~<br>~~Only permitted for use in medicines limited to oral routes of administration.~~<br>~~The maximum recommended daily dose of the medicine must not contain more than 300mg of Nicotinamide riboside chloride.~~<br>~~The following warning statement is required on the medicine label:~~<br>~~- (CHILD3) 'Not for use in children under the age of 12'.~~<br>~~When the maximum recommended daily dose of the medicine provides greater than 230mg of nicotinamide riboside chloride, the following warning statement is required on the medicine label:~~<br>~~- (PREG) 'Not recommended for use during pregnancy or lactation'.~~ | December 2021.<br>Ribose is a mandatory component of nicotinamide riboside chloride.<br>Only permitted for use in medicines limited to oral routes of administration.<br>The maximum recommended daily dose of the medicine must not provide more than 300 mg of nicotinamide riboside chloride.<br>The following warning statement (or words to the same effect) is required on the medicine label:<br>- (NTAKEN12) 'Not to be taken by children under 12 years old.'<br>When the maximum recommended daily dose of the medicine provides greater than 230 mg of nicotinamide riboside chloride, the following warning statement is required on the medicine label:<br>- (PREG) 'Not recommended for use during pregnancy or lactation'. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| nonfat dry milk | Change | E, H | E, H | ~~If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| omega-3-acid ethyl esters 90 | Change | A | A | ~~Only for use in oral medicines. The maximum recommended daily dose must not exceed 4000 mg of Omega-3-acid ethyl esters 90, AND must not provide more than 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.~~<br>~~The medicine requires the following warning statements on the medicine label: -~~<br>~~'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect).~~<br>~~- 'To be taken with food' (or~~ | Only for use in oral medicines.<br>The maximum recommended daily dose of the medicine must not provide more than:<br>a) 4000 mg of omega-3-acid ethyl esters 90; and<br>b) 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.<br>The following warning statements (or words to the same effect) are required on the medicine label:<br>- (ACOAG) 'Individuals taking anticoagulants should seek medical advice before taking this product.'<br>- (FOOD) 'To be taken with food.' | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~words to that effect).~~<br>~~- 'Not recommended for used by pregnant and lactating women' (or words to that effect).~~<br>~~- 'Use in children under 12 years is not recommended' (or words to that effect).~~ | - (PREG) 'Not recommended for use during pregnancy or lactation.'<br>- (CHILD3) 'Use in children under 12 years is not recommended.' | |
| palmidrol | Change | A | A | ~~Only to be used in a medicine where Pharmako Biotechnologies Pty Ltd (Client ID 62358), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021.~~<br>~~Only permitted for use in medicines limited to oral routes of administration.~~<br>~~The maximum recommended~~ | Only to be used in a medicine where Pharmako Biotechnologies Pty Ltd (Client ID 62358), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021.<br>Only permitted for use in medicines limited to oral routes of administration.<br>The maximum recommended daily dose of the medicine must | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~daily dose of the medicine must not contain more than 600 mg of palmidrol.~~<br>~~The following warning statements are required on the medicine label:~~<br>~~- 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use' (or words to that effect).~~<br>~~- (ADULT) 'Adults only' (or words to that effect)~~<br>~~- 'Not to be used for more than 21 consecutive days' (or words to that effect).~~ | not provide more than 600 mg of palmidrol.<br>The following warning statements (or words to the same effect) are required on the medicine label:<br>- (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.'<br>- (ADULT) 'Adults only.'<br>- (21DAYS) 'Not to be used for more than 21 consecutive days.' | |
| para-propyl anisole | Change | E | E | ~~Permitted for use only in combination with other permitted ingredients as a fragrance.~~<br>~~If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.~~ | Para-propyl anisole must only be included in medicines when in combination with other permitted ingredients as a fragrance and/or flavour proprietary excipient formulation.<br>The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | | medicine.<br>The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine. | |
| peanut | Change | E | E | ~~The medicine requires the following warning statement on the medicine label:<br>- (PEANUT) 'Contains Peanut' (or words to that effect).~~ | | |
| permethrin | Change | E | E | ~~The concentration of in the medicine must be no more than 2%.~~ | The total concentration of permethrin in the medicine must not be more than 2%. | |
| phenylalanine | Change | A, E | A, E | ~~When for oral ingestion the medicine requires the following warning statement on the medicine label:<br>- (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect).<br>When the medicine contains more than 500mg in the maximum recommended~~ | When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label:<br>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant'. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~daily dose it requires the following warning statement on the medicine label:~~<br>~~- (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.~~ | | |
| poliglusam | Change | A, E | A, E | ~~The average molecular mass of poliglusam must be greater than 2 kilodaltons.~~<br>~~When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose.~~<br>~~When for internal use, the following warning statements are required on the medicine label:~~<br>~~- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and~~<br>~~- (SFOOD) 'Derived from seafood'.~~<br>~~When for internal use and the dosage form is a powdered preparation, the medicine~~ | The average molecular mass of poliglusam must be greater than 2 kilodaltons.<br>When for internal use:<br>(a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and<br>(b) the following warning statement is required on the medicine label:<br>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect).<br>When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label: | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~requires the following warning statements on the medicine label:~~<br>~~- (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.~~<br>~~When used as an excipient, only for use in topical medicines for dermal application.~~ | - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.<br>When used as an excipient, only for use in topical medicines for dermal application. | |
| poliglusam derived from aspergillus niger | Change | A, E | A, E | ~~When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from Aspergillus niger per maximum recommended daily dose and requires the following warning statement on the medicine label:~~<br>~~- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect).~~<br>~~If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the~~ | When for oral use:<br>(a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger;<br>(b) the following warning statement (or words to the same effect) is required on the medicine label:<br>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication.'; and<br>(c) if the medicine is a powdered dosage form, the following warning statement is | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~medicine label:~~<br>~~- 'Do not take powder alone. Mix with food or fluid.'~~<br>~~When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.~~ | also required on the medicine label:<br>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.'<br>When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application. | |
| potassium chloride | Change | A, E, H | A, E, H | ~~When for oral use:~~<br>~~a) potassium is a mandatory component of potassium chloride;~~<br>~~b) the medicine requires the following warning statement on the medicine label:~~<br>~~- (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and~~<br>~~c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage~~ | When for oral use:<br>(a) potassium is a mandatory component of potassium chloride;<br>(b) the medicine requires the following warning statement on the medicine label:<br>- (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and<br>(c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~unit.~~<br>~~Medicines for use as oral rehydration therapy, are subject to the following conditions:~~<br>~~a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;~~<br>~~b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and~~<br>~~c) the medicine requires the warning statements:~~<br>~~- (UOAD) 'Use only as directed'~~ | mg.<br>Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions:<br>(a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;<br>(b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and<br>(c) the following warning statements are required on the medicine label:<br>- (UOAD) 'Use only as directed'<br>- (DIAR3) 'If diarrhoea persists, seek medical advice.' | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~- (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.~~ | When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%. | |
| potassium sorbate | Change | E | E | ~~The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.~~ | | |
| propyl hydroxybenzoate | Change | E | E | ~~Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | | |
| Protease | Change | A | A | ~~Must be derived from Aspergillus oryzae or Aspergillus niger.~~<br>~~When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted.~~<br>~~When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.~~ | Must be derived from Aspergillus oryzae or Aspergillus niger. | |
| psoralen (of Cullen corylifolium) | Removal | | E | - | | |
| purified honey | Change | A, E | A, E | ~~When the route of administration is oral, the medicine requires the following warning statement~~ | When the route of administration is oral, the following warning statement is required on the medicine label: | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on the medicine label:~~<br>~~- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| riboflavin sodium phosphate | Change | A, E | A, E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| rice wine | Change | E | E | ~~Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:~~<br>~~- (ETHAN) 'Contains ethanol' or 'contains alcohol'~~ | Ethanol is a mandatory component of rice wine. | |
| saccharin | Change | E | E | ~~When the medicine is for oral use, the following warning statement is required on the medicine label:~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~- (SACCH) 'Contains saccharin' (or words to that effect).~~ | | |
| saccharin sodium | Change | E | E | ~~The medicine requires the following warning statement on the medicine label:~~<br>~~- (SACCH) 'Contains saccharin' (or words to that effect).~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium acetate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium acid citrate | Change | A, E, H | A, E, H | ~~When used as an active ingredient, only for use in oral medicines.~~ ~~When used as an active, only for use in oral medicines.~~ ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | When sodium acid citrate is used as an active ingredient, only for use in oral medicines. | |
| sodium ascorbate | Change | A, E, H | A, E, H | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium benzoate | Change | E | E | ~~Medicines containing benzoates require the following warning statement on the medicine label:~~<br>~~- (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium beta-hydroxy-beta-methylbutyrate | Change | A, H | A, H | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium bicarbonate | Change | A, E | A, E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement~~ | When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.<br>Medicines containing sodium | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~<br>~~When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.~~<br>~~Medicines for use as oral rehydration therapy are subject to the following conditions:~~<br>~~a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;~~<br>~~b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the~~ | bicarbonate for use as oral rehydration therapy are subject to the following conditions:<br>a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;<br>b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'<br>c) the following warning statements are required on the medicine label:<br>- (UOAD) 'Use only as directed.'<br>- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'~~<br>~~c) the medicine requires the following warning statements on the medicine label:~~<br>~~- (UOAD) 'Use only as directed.'~~<br>~~- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'~~<br>~~- (DIAR3) 'If diarrhoea persists, seek medical advice.'~~ | children over 6 years - seek medical advice (or words to that effect).'<br>- (DIAR3) 'If diarrhoea persists, seek medical advice.' | |
| sodium bisulfite | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.~~ | | |
| sodium carbonate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium carbonate monohydrate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium citrate | Change | A, E | A, E | ~~Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The~~ | When for use as an active ingredient, only for oral use. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium citrate dihydrate | Change | A, E | A, E | ~~Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium cyclamate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium erythorbate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium fluoride | Change | A, E, H | A, E, H | ~~Fluoride is a mandatory component of Sodium fluoride.~~<br>~~Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene.~~<br>~~When used as an active~~ | Fluoride is a mandatory component of sodium fluoride.<br>The route of administration must be limited to dental.<br>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.<br>When used as an active ingredient, the medicine is | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~ingredient, it is subject to the following conditions:~~<br>~~a) Only for use in combination with at least one other listable therapeutically active ingredient.~~<br>~~b) The concentration of fluoride ion must be no more than 1,500 mg/kg.~~<br>~~When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:~~<br>~~- (DNTSW) 'Do not swallow.'~~<br>~~- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state~~ | subject to the following conditions:<br>(a) only for use in combination with at least one other active ingredient; and<br>(b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.<br>When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:<br>- (DNTSW) 'Do not swallow.'<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium fumarate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium glycerophosphate | Change | A, E, H | A, E, H | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium hydroxide | Change | E | E | ~~The concentration in the medicine must be no more than 5%.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~<br>~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.~~ | The concentration of sodium hydroxide in the medicine must not be more than 5%.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| sodium hypochlorite | Change | E | E | ~~Chlorine is a mandatory component of Sodium hypochlorite.~~<br>~~The concentration of chlorine in the medicine must be no more than 4%.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | Chlorine is a mandatory component of sodium hypochlorite.<br>The concentration of chlorine in the medicine must not be more than 4%. | |
| sodium lactate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium laureth sulfate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium lauryl phosphate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium lauryl sulfate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium metabisulfite | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.~~ | | |
| sodium methyl hydroxybenzoate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~hydroxybenzoates require the following warning statement on the medicine label:~~<br>~~- (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | | |
| sodium monofluorophosphate | Change | A | A | ~~Fluoride is a mandatory component of sodium monofluorophosphate.~~<br>~~Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene.~~<br>~~When used as an active ingredient, it is subject to the following conditions:~~<br>~~a) Only for use in combination with at least one other listable therapeutically active ingredient.~~<br>~~b) The concentration of~~ | Fluoride is a mandatory component of sodium monofluorophosphate.<br>The route of administration must be limited to dental.<br>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.<br>When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions:<br>(a) only for use in combination with at least one other active ingredient; and | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~fluoride ion must be no more than 1,500 mg/kg.~~<br>~~When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:~~<br>~~- (DNTSW) 'Do not swallow.'~~<br>~~- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.<br>When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label:<br>- (DNTSW) 'Do not swallow.'<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' | |
| sodium pantothenate | Change | A, E, H | A, E, H | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium perborate | Change | A, H | A, H | ~~Boron is a mandatory component of sodium perborate.~~<br>~~When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron.~~<br>~~When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the~~ | Boron is a mandatory component of sodium perborate.<br>When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron.<br>When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%.<br>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:<br>- is listed in the Register on or after 2 March 2020; or | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~medicine requires the following warning statement on the label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~<br>~~The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:~~<br>~~- is listed in the Register on or after 2 March 2020; or~~<br>~~- is supplied after 2 March 2021.~~<br>~~(a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:~~<br>~~- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or~~<br>~~- (ADULT) 'Adults only' (or~~ | - is supplied after 2 March 2021.<br>(a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:<br>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or<br>- (ADULT) 'Adults only' (or words to that effect).<br>(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:<br>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or<br>- (ADULT) 'Adults only' (or words to that effect). | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~words to that effect).~~<br>~~(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:~~<br>~~- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or~~<br>~~- (ADULT) 'Adults only' (or words to that effect).~~<br>~~(c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:~~<br>~~- (BORON) 'Contains boron' (or words to that effect).~~<br>~~(d) When the medicine is for topical use for dermal application, the following~~ | (c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:<br>- (BORON) 'Contains boron' (or words to that effect).<br>(d) When the medicine is for topical use for dermal application, the following warning statement is required on the label:<br>- (BROKEN) 'Use on unbroken skin only' (or words to that effect). | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~warning statement is required on the label:~~<br>~~- (BROKEN) 'Use on unbroken skin only' (or words to that effect).~~ | | |
| Sodium propionate | Change | E | E | ~~Only for use in topical medicines for dermal application.~~ | | |
| sodium propyl hydroxybenzoate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~<br>~~Medicines containing hydroxybenzoates require the following warning statement on the medicine label:~~<br>~~- (TOTBNZ) 'Contains~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.~~ | | |
| sodium silicate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'~~ | | |
| sodium starch glycollate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium starch glycollate type A | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium sulfate | Change | A, E, H | A, E, H | ~~When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have~~ | When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
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| | | | | ~~a laxative effect'.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium'~~<br>~~(or words to that effect).~~ | | |
| sodium sulfate decahydrate | Change | A, E, H | A, E, H | ~~When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label:~~<br>~~- (LAX4) 'Substance may have a laxative effect'.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~ | When it is not intended to be a laxative, the following warning statement is required on the medicine label:<br>- (LAX4) 'Substance may have a laxative effect'. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| sodium sulfite | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~<br>~~Medicines containing sulfites salts require the following warning statement on the medicine label:~~<br>~~- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~medicine contains one sulfite source.~~ | | |
| sodium sulfite heptahydrate | Change | E | E | ~~Only for use in topical medicines for dermal application.~~<br>~~Medicines containing sulfites salts require the following warning statement on the medicine label:~~<br>~~- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.~~ | Only for use in topical medicines for dermal application. | |
| sorbic acid | Change | E | E | ~~The medicine requires the following warning statement on the medicine label:~~<br>~~- (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]'~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~(or words to this effect) if medicine contains one sorbate source.~~ | | |
| sorbitol solution (70 per cent) (crystallising) | Change | A, E | A, E | ~~Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (crystallising).~~<br>~~When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.~~<br>~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a~~ | Sorbitol is a mandatory component of sorbitol solution (70 per cent) (crystallising).<br>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~laxative effect or cause diarrhoea (or words to that effect).'~~ | | |
| sorbitol solution (70 per cent) (non-crystallising) | Change | A, E | A, E | ~~Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (non-crystallising).~~<br>~~When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.~~<br>~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a~~ | Sorbitol is a mandatory component of sorbitol solution (70 per cent) (non-crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~laxative effect or cause diarrhoea (or words to that effect).'~~ | | |
| sucrose | Change | E | E | ~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:<br>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:<br>- (LACT) 'Contains lactose' (or words to that effect).~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| sucrose laurate | Change | E | E | ~~When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| sucrose octaacetate | Change | E | E | ~~When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| Sugarcane | Change | E, H | E, H | ~~When for oral or sublingual use, sucrose is a mandatory component of Sugarcane.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | When for oral or sublingual use, sucrose is a mandatory component of sugarcane. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| sulfur dioxide | Change | E | E | ~~Medicines containing sulfites salts require the following warning statement on the medicine label:~~<br>~~- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.~~ | | |
| tartrazine | Change | E | E | ~~Permitted for use only as a colour in medicines limited to topical and oral routes of administration.~~<br>~~The medicine requires the following warning statement on the medicine label:~~<br>~~- (TART) 'Contains tartrazine' (or words to that effect).~~ | Only for use as a colour.<br>Only for use in medicines for topical and oral administration. | |
| tartrazine aluminium lake | Change | E | E | ~~Permitted for use only as a colour in medicines limited to topical and oral routes of administration.~~<br>~~The medicine requires the~~ | Only for use as a colour.<br>Only for use in medicines for topical and oral administration. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).~~ | | |
| tetrasodium pyrophosphate | Change | E | E | ~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | | |
| Tilactase | Change | A | A | ~~Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted. When the dosage form is~~ | Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~divided, the units 'acid lactase units' and 'thousand acid lactase units' are permitted.~~ | | |
| treacle | Change | E | E | ~~When for oral or sublingual use, sucrose is a mandatory component of Treacle.~~<br>~~When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.~~<br>~~If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:~~ | When for oral or sublingual use, sucrose is a mandatory component of treacle. | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| tribasic sodium phosphate | Change | E | E | ~~When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.~~<br>~~When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.~~<br>~~When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:~~<br>~~- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).~~ | When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. | |
| whole dry milk | Change | E | E | ~~If the product is for oral ingestion and contains lactose, then the medicine requires the following~~ | | |

| Ingredient name | Change type | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
|---|---|---|---|---|---|---|
| | | | | ~~warning statement on the medicine label:~~<br>~~- (LACT) 'Contains lactose' (or words to that effect).~~ | | |
| xylitol | Change | E | E | ~~When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:~~<br>~~- (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.~~ | | |