



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|---------------------------------------|
| Summary for ARTG Entry: | 383994 | Swisse Nutra+ 2'-FL + Zinc Gut Repair |
| ARTG entry for | Medicine Listed | |
| Sponsor | Swisse Wellness Pty Ltd | |
| Postal Address | L6 & 7 88 Langridge Street, Collingwood, VIC, 3066 Australia | |
| ARTG Start Date | 15/02/2022 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Listed Medicines | |

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Swisse Nutra+ 2'-FL + Zinc Gut Repair

| Product Type | Single Medicine Product | Effective Date | 13/06/2023 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support general health and wellbeing
- Maintain/support smell sensation
- Maintain/support taste sensation
- Helps enhance/promote gastrointestinal system mucosa health
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal mucosal membrane health
- Aids/assists repair of gastrointestinal/gut wall lining
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Label statement: If symptoms persist, talk to your health professional.
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Warnings

Contains lactose (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--------------------------|---------------|
| 2'-fucosyllactose | 600 mg |
| Equivalent: lactose | 18 mg |
| Peppermint Oil | 15 mg |
| polaprezinc | 75 mg |
| Equivalent: zinc | 16.94 mg |

Other Ingredients (Excipients)

colloidal anhydrous silica

magnesium stearate

maltodextrin

microcrystalline cellulose

Steviol glycosides

tapioca starch

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary