



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	27/07/2022
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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

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).

Product presentation must not imply or refer to serious immunological diseases.

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



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Warnings

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
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

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