



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	337270	Swisse Nutra+ Pro Strength Vitamin C + D Complex
ARTG entry for	Medicine Listed	
Sponsor	Swisse Wellness Pty Ltd	
Postal Address	L6 & 7 88 Langridge Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	30/05/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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+ Pro Strength Vitamin C + D Complex

Product Type	Single Medicine Product	Effective Date	30/05/2020
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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 immune system health
- Maintain/support healthy immune system function
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of common cold symptoms
- Decrease/reduce/relieve symptoms of common cold

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

calcium ascorbate dihydrate	363 mg/g
Equivalent: ascorbic acid	300 mg/g
colecalfiferol	.005 mg/g
sodium ascorbate	113.1 mg/g
Equivalent: ascorbic acid	100 mg/g
zinc citrate dihydrate	25.64 mg/g
Equivalent: zinc	8 mg/g

Other Ingredients (Excipients)

Acacia

citric acid

colloidal anhydrous silica

dl-alpha-tocopherol

Flavour

maize starch

maltodextrin

medium chain triglycerides

riboflavin

silicon dioxide

Siraitia grosvenorii

Stevia rebaudiana

sucrose

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