

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	337272	Swisse Nutra+ High Strength Collagen Repair
ARTG entry for	Medicine Listed	
Sponsor	Swisse Wellness Pty Ltd	
Postal Address	111 Cambridge S Australia	Street, Collingwood, VIC, 3066
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+ High Strength Collagen Repair Product Type Effective Date 4/06/2020 Single Medicine Product **Permitted Indications** Maintain/support collagen formation Maintain/support collagen health Helps decrease/reduce/relieve cartilage loss/wear/tear/damage Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis Decrease/reduce/relieve mild joint pain/soreness Indication Requirements Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Label statement: If symptoms persist, talk to your health professional. Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild. Product presentation must only refer to mild joint symptoms. **Standard Indications** No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect). Derived from seafood

Additional Product information

Pack Size/Poison information

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Components 1. Formulation 1 Dosage Form Powder, oral Route of Administration Oral Visual Identification Oral Active Ingredients 3.85 mg/g glucosamine sulfate sodium chloride 145.07 mg/g Equivalent: glucosamine sulfate sodium chloride 115.38 mg/g hydrolysed collagen 769.23 mg/g Other Ingredients (Excipients) citric acid colloidal anhydrous silica Flavour	
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Flavour	
malic acid	
maltodextrin	
povidone	
Siraitia grosvenorii	
Stevia rebaudiana	

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