



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	417392	Swisse Ultiboost High Strength Krill Oil
ARTG entry for	Medicine Assessed Listed	
Sponsor	Swisse Wellness Pty Ltd	
Postal Address	L6 & 7 88 Langridge Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	10/08/2023	
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 Ultiboost High Strength Krill Oil

Product Type	Single Medicine Product	Effective Date	26/10/2023
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Permitted Indications

Maintain/support eye health
Maintain/support general health and wellbeing
Maintain/support cardiovascular system health
Maintain/support heart health
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
Maintain/support brain health

Indication Requirements

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).

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

Decrease/reduce/relieve knee pain and stiffness in mild to moderate osteoarthritis
Increase knee physical function in mild to moderate osteoarthritis

Warnings

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.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Contains crustacea OR Contains crustacean products.

Additional Product information



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

euphausia superba oil **1000 mg**

Other Ingredients (Excipients)

d-alpha-tocopherol

Gelatin

glycerol

purified water

sorbitol solution (70 per cent) (non-crystallising)

Soya Oil

vanillin

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