



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	151555	Smart Adult
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Phytoceuticals Pty Ltd	
Postal Address	37 Desmond Street, MERRYLANDS, NSW, 2160 Australia	
ARTG Start Date	10/04/2008	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Smart Adult

Product Type	Single Medicine Product	Effective Date	10/04/2008
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

- For the symptomatic relief of dry skin.
- May assist in the management of dry skin.
- May assist in maintaining peripheral circulation and promoting general health.
- May assist blood circulation.
- Aids, assists or helps in the maintenance or improvement of general well-being.
- Aids or assists in the maintenance of peripheral circulation.
- May help reduce joint inflammation associated with arthritis.
- Temporary relief of the pain of arthritis. (or) Temporary relief of arthritic pain. [Warning S required]

Specific Indications

No Specific Indications included on Record

Warnings

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Public Summary



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Medicine component

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

natural fish oil	1 g
Equivalent: eicosapentaenoic acid	180 mg
Equivalent: docosahexaenoic acid	120 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

Gelatin

glycerol

lecithin

Orange Oil

purified water

sucralose

sunset yellow FCF

titanium dioxide

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