



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|------------|
| Summary for ARTG Entry: | 228307 | LymphaDerm |
| ARTG entry for | Medicine Listed | |
| Sponsor | FIT-BioCeuticals Limited | |
| Postal Address | Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia | |
| ARTG Start Date | 23/09/2014 | |
| 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 . LymphaDerm

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 20/10/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
Aid/assist/helps connective tissue production/formation
Traditionally used in Western herbal medicine to maintain/support healthy lymphatic system
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild psoriasis
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing
Traditionally used in Western herbal medicine to aid/assist flushing of the urinary tract

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must only refer to mild eczema.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to drugs/alcohol.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must only refer to mild psoriasis

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|-----------------------|
| Arctium lappa root Extract dry concentrate | 200 mg |
| Equivalent: Arctium lappa (Dry) | 1 g |
| Echinacea purpurea herb Extract dry concentrate standardised | 83.34 mg |
| Equivalent: Echinacea purpurea (Dry) | 1 g |
| Galium aparine herb Extract dry concentrate | 400 mg |
| Equivalent: Galium aparine (Dry) | 2 g |
| Phytolacca americana root Extract dry concentrate | 33.3 microgram |
| Equivalent: Phytolacca americana (Dry) | 333 microgram |
| retinol acetate | 172 microgram |
| Equivalent: vitamin A | 150.05 RE |
| Rumex crispus root and rhizome Extract dry concentrate | 300 mg |
| Equivalent: Rumex crispus (Dry) | 1.5 g |
| zinc amino acid chelate | 16.5 mg |
| Equivalent: zinc | 3.3 mg |

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

dl-alpha-tocopherol

hypromellose

macrogol 400

magnesium stearate

maize starch

maltodextrin

microcrystalline cellulose

povidone

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