



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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
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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

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



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If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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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