

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 388551 Liposomal C

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 17/05/2022
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 . Liposomal C

Product Type Single Medicine Product Effective Date 17/05/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support collagen formation

Maintain/support energy levels

Relieve weariness/tiredness/fatigue/feeling of weakness

Maintain/support connective tissue health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Decrease/reduce/relieve common cold duration

Maintain/support wound healing

Indication Requirements

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

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

Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	
Active Ingredients	

sodium ascorbate256 mg/mLEquivalent: ascorbic acid200 mg/mL

Other Ingredients (Excipients)

Additional Product information

ethanol glycerol lecithin Lemon Oil purified water

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