



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		233362	Lipoec 400
ARTG entry for	Medicine Listed		
Sponsor	FIT-BioCeuticals Pty Ltd		
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia		
ARTG Start Date	2/02/2015		
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 . Lipoec 400

Product Type	Single Medicine Product	Effective Date	1/07/2024
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps convert (state food) into energy
Aid/assist/helps glucose/sugar/carbohydrate metabolism

Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

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alpha lipoic acid 400 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- Gelatin
- magnesium stearate
- microcrystalline cellulose
- purified water
- silicon dioxide
- sodium lauryl sulfate
- titanium dioxide

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