



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377230	Organic Evening Primrose Oil
ARTG entry for	Medicine Listed	
Sponsor	Melrose Laboratories Pty Ltd	
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
ARTG Start Date	1/11/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Organic Evening Primrose Oil

Product Type	Single Medicine Product	Effective Date	1/11/2021
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Permitted Indications

Maintain/support general health and wellbeing
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support female healthy hormonal balance
Helps reduce occurrence of premenstrual tension symptoms
Decrease/reduce/relieve skin peeling/cracking
Helps reduce occurrence of skin dryness
Maintain/support skin firmness
Maintain/support skin health
Maintain/support skin integrity/structure

Indication Requirements

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

If product is indicated for supplementation, 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

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 Liquid, multipurpose

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Route of Administration Oral
Topical

Visual Identification

Active Ingredients

Evening Primrose Oil 886.0523 mg/mL

Other Ingredients (Excipients)

Flavour

mixed (low-alpha type) tocopherols concentrate
thaumatin

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