



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	174751	Gold Evening Primrose Oil
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Bomax Pty Ltd	
Postal Address	6 Patya Close, EPPING, NSW, 2121 Australia	
ARTG Start Date	11/08/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Gold Evening Primrose Oil

Product Type	Single Medicine Product	Effective Date	11/08/2010
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

WELL - Aids or assists in maintenance or improvement of general well-being.
SKIN1 - For the symptomatic relief of eczema
SKIN3 - For the symptomatic relief of dermatitis
SKIN9 - May assist in the management of eczema
SKIN11 - May assist in the management of dermatitis
MENS4 - Relief of premenstrual breast pain
MENS5 - For the symptomatic relief of pre-menstrual syndrome)
MENS9 - May assist in the management of pre-menstrual syndrome
ARTH1 - Aids in the temporary relief of the pain of arthritis OR Temporary relief of arthritic pain
RHEUM4 - May assist in the management of rheumatism
RHEUM - Temporary relief of rheumatism OR Temporary relief of rheumatic pain
ARTH4 - May help increase joint mobility associated with arthritis
RHEUM2 - Symptomatic relief of rheumatism
* Evening Primrose oil is a valuable source of the omega 6 fatty acid gamma-Linolenic acid.
* Supports the healing and repair of the skin.
* May assist in the relief of flaking, scaling and itching of the skin.
* Relief of pre-menstrual symptoms/syndrome.
* Assists in the maintenance of a healthy cardiovascular system

Warnings



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No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 .

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	Clear size 22 minim oblong soft-gelatin capsule containing yellowish oil

Active Ingredients

Evening Primrose Oil	1 g
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Other Ingredients (Excipients)

d-alpha-tocopherol
Gelatin
glycerol
purified water
Soya Oil

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