



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373975	METAGENICS LIPOGEN
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	1/09/2021	
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 . METAGENICS LIPOGEN

Product Type	Single Medicine Product	Effective Date	7/06/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes
Traditionally used in Chinese medicine to maintain/support natural liver cleansing/detoxification processes
Traditionally used in Ayurvedic medicine to maintain/support natural liver cleansing/detoxification processes
Traditionally used in Chinese medicine to maintain/support healthy digestion
Traditionally used in Western herbal medicine to maintain/support healthy digestion
Maintain/support healthy digestion
Aid/assist fat distribution and assimilation in the digestive system
Traditionally used in Western herbal medicine to maintain/support gallbladder function
Traditionally used in Chinese medicine to maintain/support gallbladder function
Traditionally used in Chinese medicine to liver tonic/Enhance liver health
Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
Traditionally used in Ayurvedic medicine to liver tonic/Enhance liver health
Maintain/support healthy liver function
Traditionally used in Chinese medicine to maintain/support healthy liver function
Traditionally used in Western herbal medicine to maintain/support healthy liver function
Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
Traditionally used in Ayurvedic medicine to maintain/support liver health
Traditionally used in Western herbal medicine to maintain/support liver health
Helps decrease/reduce homocysteine levels
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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).

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.



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Product presentation must not imply or refer to drugs/alcohol.
 Product presentation must not imply or refer to disease in any body organ.
 Product presentation must only refer to detoxification in relation to natural body processes.
 Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

Berberis vulgaris stem bark Extract dry concentrate	100 mg
Equivalent: Berberis vulgaris (Dry)	1 g
Bupleurum falcatum root Extract dry concentrate	150 mg
Equivalent: Bupleurum falcatum (Dry)	1.5 g
choline bitartrate	167.15 mg
Equivalent: choline	68.75 mg
folic acid	199.67 microgram
inositol	100 mg
mecobalamin (co-methylcobalamin)	200.1 microgram
methionine	100 mg
pyridoxine hydrochloride	25 mg
Equivalent: pyridoxine	20.57 mg
Taraxacum officinale root Extract dry concentrate	100 mg
Equivalent: Taraxacum officinale (Dry)	500 mg
taurine	100 mg

Other Ingredients (Excipients)

croscarmellose sodium
glycerol
hypromellose
magnesium stearate
microcrystalline cellulose
povidone
silicon dioxide

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