



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	219801	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	3/02/2014	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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	19/03/2020
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Permitted Indications

- Traditionally used in Ayurvedic 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 Western herbal medicine to maintain/support natural liver cleansing/detoxification processes
- Maintain/support healthy digestion
- Traditionally used in Chinese medicine to maintain/support healthy digestion
- Traditionally used in Ayurvedic medicine to maintain/support healthy digestion
- Traditionally used in Western herbal medicine to 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 Ayurvedic medicine to maintain/support gallbladder function
- Traditionally used in Chinese medicine to maintain/support gallbladder function
- Maintain/support gallbladder function
- Traditionally used in Chinese medicine to liver tonic/Enhance liver health
- Traditionally used in Ayurvedic medicine to liver tonic/Enhance liver health
- Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
- Maintain/support healthy liver function
- Traditionally used in Ayurvedic medicine to 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
- Helps decrease/reduce homocysteine levels
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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

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 drugs/alcohol.

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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
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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	150 mg
cyanocobalamin	200 microgram
folic acid	200 microgram
inositol	100 mg
methionine	100 mg
pyridoxine hydrochloride	25 mg
Equivalent: pyridoxine	20.15 mg
Taraxacum officinale whole plant Extract dry concentrate	111.111 mg
Equivalent: Taraxacum officinale (Dry)	500 mg
taurine	100 mg

Other Ingredients (Excipients)

- betaine hydrochloride
- calcium hydrogen phosphate dihydrate
- croscarmellose sodium
- hypromellose
- macrogol 400
- maltodextrin
- microcrystalline cellulose
- powdered cellulose
- silicon dioxide

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stearic acid

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