



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307259	METAGENICS O-CLEAR
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/07/2018	
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 O-CLEAR

Product Type	Single Medicine Product	Effective Date	9/04/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to hepatoprotectant/protect the liver.
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver.
- Traditionally used in Ayurvedic medicine to maintain/support bile production
- Traditionally used in Western herbal medicine to maintain/support bile production
- Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Maintain/support female reproductive system health
- Maintain/support reproductive system health

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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

Curcuma longa rhizome Extract dry concentrate	60 mg
Equivalent: Curcuma longa (Dry)	1.5 g
cyanocobalamin	250 microgram
Glycine max	143.75 mg
molybdenum trioxide	94 microgram
Equivalent: molybdenum	62.5 microgram
potassium iodide	131 microgram
Equivalent: iodine	100 microgram
pyridoxal 5-phosphate monohydrate	39 mg
Equivalent: pyridoxine	25 mg
Rosmarinus officinalis leaf Extract dry concentrate	100 mg
Equivalent: Rosmarinus officinalis (Dry)	1 g
Silybum marianum	42.86 mg
zinc amino acid chelate	60 mg
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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