



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375974	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	8/10/2021	
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 . METAGENICS O-CLEAR

Product Type	Single Medicine Product	Effective Date	8/10/2021
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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 Western herbal medicine to maintain/support healthy liver function
Traditionally used in Ayurvedic 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 disease in any body organ, in particular the kidney or liver.
Product presentation must not imply or refer to infertility.
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

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

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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
Glycine max pressed seed cake Extract dry concentrate	143.75 mg
Equivalent: Glycine max (Dry)	23 g
mecobalamin (co-methylcobalamin)	250.24 microgram
molybdenum trioxide	93.77 microgram
Equivalent: molybdenum	62.5 microgram
potassium iodide	130.8 microgram
Equivalent: iodine	100 microgram
pyridoxal 5-phosphate monohydrate	39 mg
Equivalent: pyridoxine	24.88 mg
Rosmarinus officinalis leaf Extract dry concentrate	100 mg
Equivalent: Rosmarinus officinalis (Dry)	1 g
Silybum marianum seed Extract dry concentrate	42.86 mg
Equivalent: Silybum marianum (Dry)	3 g
zinc amino acid chelate	60 mg
Equivalent: zinc	12 mg
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
citric acid	
colloidal anhydrous silica	
croscarmellose sodium	
glycerol	
hypromellose	
magnesium stearate	
maltodextrin	
microcrystalline cellulose	

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