



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 only refer to detoxification in relation to natural body processes.
- 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, in particular the kidney or liver.
- Product presentation must not imply or refer to infertility.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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**Warnings**

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

**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**

<b>Curcuma longa</b>	<b>60 mg</b>
Equivalent: Curcuma longa	1.5 g
<b>cyanocobalamin</b>	<b>250 microgram</b>
<b>Glycine max</b>	<b>143.75 mg</b>
<b>molybdenum trioxide</b>	<b>94 microgram</b>
Equivalent: molybdenum	62.5 microgram
<b>potassium iodide</b>	<b>131 microgram</b>
Equivalent: iodine	100 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>39 mg</b>
Equivalent: pyridoxine	25 mg
<b>Rosmarinus officinalis</b>	<b>100 mg</b>
Equivalent: cineole	25 mg
Equivalent: camphor	12.5 mg
Equivalent: Rosmarinus officinalis	1 g
<b>Silybum marianum</b>	<b>42.86 mg</b>
<b>zinc amino acid chelate</b>	<b>60 mg</b>
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

Public Summary

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