



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

## Public Summary

<b>Summary for ARTG Entry:</b>	290501	HepatoClear
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	21/06/2017	
<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.

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 . HepatoClear

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/11/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Western herbal medicine to maintain/support healthy digestion

Traditionally used in Western herbal medicine to aid/assist/helps elimination of dietary fat

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver

Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic

Traditionally used in Western herbal medicine to maintain/support healthy liver function

### Indication Requirements

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Adults only.

Not recommended for use by pregnant and lactating women (or words to that effect).

### Additional Product information



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Cynara scolymus leaf Extract dry concentrate standardised	10 mg/g
Equivalent: Cynara scolymus (Fresh)	500 mg/g
glutathione	5 mg/g
Rosmarinus officinalis leaf Extract dry concentrate	80 mg/g
Equivalent: Rosmarinus officinalis (Dry)	400 mg/g
Schisandra chinensis fruit Extract dry concentrate	125 mg/g
Equivalent: Schisandra chinensis (Dry)	500 mg/g
selenomethionine	24.84 microgram/g
Equivalent: selenium	10 microgram/g
Silybum marianum fruit Extract dry concentrate standardised	202.02 mg/g
Equivalent: Silybum marianum (Dry)	8080.8 mg/g
taurine	100 mg/g
Other Ingredients (Excipients)	
citric acid	
colloidal anhydrous silica	
Flavour	
glycine	
inulin	
lecithin	
maltodextrin	
Steviol glycosides	

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