



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	290501	HepatoClear
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	21/06/2017	
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 . HepatoClear

Product Type	Single Medicine Product	Effective Date	10/06/2020
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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 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.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only (or words to that effect).
This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be



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exceeded.

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

Additional Product information

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	10 mg/g
Equivalent: Cynara scolymus	500 mg/g
Equivalent: Caffeoylquinic acids calculated as cynarin of Cynara scolymus	500 microgram/g
glutathione	5 mg/g
Rosmarinus officinalis	80 mg/g
Equivalent: cineole	290 microgram/g
Equivalent: Rosmarinus officinalis	400 mg/g
Equivalent: camphor	272 microgram/g
Schisandra chinensis	125 mg/g
Equivalent: Schisandra chinensis	500 mg/g
selenomethionine	24.84 microgram/g
Equivalent: selenium	10 microgram/g
Silybum marianum	202.02 mg/g
taurine	100 mg/g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

glycine

inulin

lecithin

maltodextrin

Steviol glycosides

Public Summary

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