



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|------------|
| Summary for ARTG Entry: | 345127 | Liver Care |
| ARTG entry for | Medicine Listed | |
| Sponsor | FIT-BioCeuticals Limited | |
| Postal Address | Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia | |
| ARTG Start Date | 30/09/2020 | |
| 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.

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 . Liver Care

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 30/09/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
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 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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

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|------------------|------------------------|
| Pack Size | Poison Schedule |
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Components

1 . Formulation 1

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|--------------------|---------------------|
| Dosage Form | Tablet, film coated |
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|--------------------------------|------|
| Route of Administration | Oral |
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Visual Identification



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Active Ingredients

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|--|-----------------|
| Coffea arabica seed Extract dry concentrate standardised | 51.02 mg |
| Equivalent: Coffea arabica (Dry) | 2.551 g |
| d-alpha-tocopheryl acid succinate | 180 mg |
| Silybum marianum fruit Extract dry concentrate standardised | 375 mg |
| Equivalent: Silybum marianum (Dry) | 26.25 g |
| zinc amino acid chelate | 100 mg |
| Equivalent: zinc | 20 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
ethylcellulose
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose

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