Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 251812 LivProtect

ARTG entry for Medicine Listed

Sponsor FIT-BioCeuticals Pty Ltd

Postal Address Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102

Australia

ARTG Start Date 29/07/2015

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 . LivProtect

Product Type Single Medicine Product **Effective Date** 10/10/2025

Permitted Indications

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

Traditionally used in Western herbal medicine to aid/assist digestion/breakdown of dietary fat

Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of indigestion/dyspepsia

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 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.

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only

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

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Produced at 12.10.2025 at 04:07:19 AEDT



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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Or

Visual Identification

Active Ingredients

 Bupleurum falcatum root Extract dry concentrate
 20 mg

 Equivalent: Bupleurum falcatum (Dry)
 200 mg

 Cynara scolymus leaf Extract dry concentrate standardised
 80 mg

 Equivalent: Cynara scolymus (Fresh)
 4 g

 glutathione
 20 mg

 Silybum marianum fruit Extract dry concentrate standardised
 180 mg

 Equivalent: Silybum marianum (Dry)
 7.2 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

povidone

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