

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 352116 LIVER PLEX

ARTG entry for Medicine Listed

 Sponsor
 The Pharmaceutical Plant Company Pty Ltd

 Postal Address
 3 Sigma Drive, Croydon South, VIC, 3136

Australia

ARTG Start Date 22/12/2020
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 PLEX

Product Type Single Medicine Product Effective Date 22/12/2020

Permitted Indications

Traditionally used in Western herbal medicine to aids/assists natural body cleansing/detoxification processes

Traditionally used in Ayurvedic medicine to asrakhara/purifies blood

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Ayurvedic medicine to helps enhance/improve/promote/increase bile secretion/flow

Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow

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

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must only refer to detoxification in relation to natural body processes.

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

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 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

Contains ethanol or contains alcohol.

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

Additional Product information

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Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormOral LiquidRoute of AdministrationOral

Visual Identification

Active Ingredients

Curcuma longa root Extract liquid
Equivalent: Curcuma longa (Dry)
Cynara scolymus leaf Extract liquid

Equivalent: Cynara scolymus (Dry)

Silybum marianum seed Extract liquid

Equivalent: Silybum marianum (Dry)

Taraxacum officinale root Extract liquid

Equivalent: Taraxacum officinale (Dry)

100 microlitre/mL

100 mg/mL

26.7 microlitre/mL

13.35 mg/mL 300 microlitre/mL

300 mg/mL 150 microlitre/mL 150 mg/mL

Other Ingredients (Excipients)

ethanol glycerol purified water

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