

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 380173 Thompson's Liver Cleanse

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

Australia

ARTG Start Date 3/12/2021
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. Thompson's Liver Cleanse

Product Type Single Medicine Product Effective Date 29/08/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Traditionally used in Western herbal medicine to helps maintain/support body's natural channels of elimination

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

Traditionally used in Western herbal medicine to maintain/support natural body cleansing/detoxification processes

Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes

Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products

Traditionally used in Western herbal medicine to aids/assists body waste elimination

Traditionally used in Western herbal medicine to maintain/support body waste elimination

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing

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

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

Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions

Traditionally used in Western herbal medicine to maintain/support digestive system health

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal feeling of fullness

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

Linked indication - Decrease/reduce/relieve flatulence/carminative

Linked indication - Relieve digestive discomfort

Linked indication - Decrease/reduce/relieve abdominal feeling of fullness Linked indication - Decrease/reduce/relieve abdominal bloating/distention

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

Traditionally used in Western herbal medicine to relieve digestive discomfort

Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder

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

Page 1 of 3



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Traditionally used in Western herbal medicine to maintain/support liver health

Indication Requirements

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

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

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

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

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.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to disease in any body organ.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Cynara scolymus leaf Extract dry concentrate	42.86 mg
Equivalent: Cynara scolymus (Fresh)	1.5 g
Schisandra chinensis fruit Extract dry concentrate	83.4 mg
Equivalent: Schisandra chinensis (Dry)	500 mg
Silybum marianum seed Extract dry concentrate standardised	175 mg
Equivalent: Silybum marianum (Dry)	12.25 g
Taraxacum officinale root Extract dry concentrate	12.5 mg
Equivalent: Taraxacum officinale (Dry)	50 mg
taurine	100 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

purified water

silicon dioxide

sodium starch glycollate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.



Department of Health and Aged Care

Therapeutic Goods Administration