Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 368194 Oriental Botanicals Liver Tonic

ARTG entry for Medicine Listed

Sponsor McPherson's Consumer Products Pty Ltd

Postal Address Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 4/06/2021
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 . Oriental Botanicals Liver Tonic

Product Type Single Medicine Product Effective Date 4/06/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Chinese medicine to aids/assists natural body cleansing/detoxification processes in/of internal Heat pattern

Traditionally used in Chinese medicine to maintain/support natural body cleansing/detoxification processes in/of internal Heat pattern

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

Maintain/support natural liver cleansing/detoxification processes

Traditionally used in Chinese medicine to clear/drain heat in the gall bladder

 $Traditionally used in Chinese \ medicine \ to \ dispel/expel/disperse/clear \ internal/endogenous \ heat$

Traditionally used in Chinese medicine to clear/expel damp-heat from the liver

Traditionally used in Chinese medicine to regulate Qi

 $Traditionally used in Chinese \ medicine \ to \ regulate/soothe/smooth/disperse \ the \ flow \ of \ liver-qi/liver$

Traditionally used in Chinese medicine to move/activate/dissipate stagnant qi

Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys in/of Kidney Yin Deficiency pattern

Traditionally used in Chinese medicine to nourish/tonify/replenish kidney-yin

Traditionally used in Chinese medicine to nourish/tonify/replenish/enrich/strengthen liver-yin

Traditionally used in Chinese medicine to blood tonic/Enhance blood health

Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite

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

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

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

Traditionally used in Chinese medicine to relieve excessive belching

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

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

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

Traditionally used in Western herbal medicine to maintain/support gallbladder function

Traditionally used in Chinese medicine to maintain/support gallbladder function in/of Liver Qi Stagnation pattern

 $Traditionally \ used \ in \ Chinese \ medicine \ to \ maintain/support \ gall bladder \ health \ in/of \ Liver \ Qi \ Stagnation \ pattern$

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

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Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish liver in/of Liver Yin Deficiency pattern

Traditionally used in Western herbal medicine to liver tonic/Enhance liver health

Traditionally used in Chinese medicine to promote bile flow from liver/chloretic

Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic

Traditionally used in Chinese medicine to helps maintain/support bile secretion/flow

Traditionally used in Western herbal medicine to helps maintain/support bile secretion/flow

Traditionally used in Chinese medicine to helps maintain/support bile secretion/flow in/of Liver Qi Stagnation pattern

Traditionally used in Chinese medicine to maintain/support bile production

Traditionally used in Chinese medicine to maintain/support healthy liver function in/of Liver Qi Stagnation pattern

Maintain/support healthy liver function

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

Maintain/support liver health

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

Traditionally used in Chinese medicine to maintain/support liver health

Traditionally used in Chinese medicine to decrease/reduce/relieve nausea

Traditionally used in Chinese medicine to relieve irritability in/of Liver Qi Stagnation pattern

Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods in/of Liver Qi Stagnation pattern

Indication Requirements

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 drugs/alcohol.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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 imply or refer to disease in any body organ.

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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 sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

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Bupleurum falcatum root Extract dry concentrate	50 mg
Equivalent: Bupleurum falcatum (Dry)	500 mg
Citrus reticulata fruit peel Extract dry concentrate	100 mg
Equivalent: Citrus reticulata (Dry)	500 mg
Lycium barbarum fruit Extract dry concentrate	200 mg
Equivalent: Lycium barbarum (Dry)	1 g
Schisandra chinensis fruit Extract dry concentrate	100 mg
Equivalent: Schisandra chinensis (Dry)	500 mg
Scutellaria baicalensis root Extract dry concentrate	100 mg
Equivalent: Scutellaria baicalensis (Dry)	500 mg
Silybum marianum seed Extract dry concentrate	100 mg
Equivalent: Silybum marianum (Dry)	6 g
Taraxacum mongolicum whole plant Extract dry concentrate	100 mg
Equivalent: Taraxacum mongolicum (Dry)	500 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

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