Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 218993 Mediherb P2-Detox

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 8/01/2014

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Mediherb P2-Detox

Product Type Single Medicine Product Effective Date 22/06/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Aids/assists natural body cleansing/detoxification processes

Maintain/support natural body cleansing/detoxification processes

Maintain/support natural liver cleansing/detoxification processes

Anti-inflammatory/relieve inflammation

Aid/assist fat emulsification in the digestive system

Maintain/support gastrointestinal mucosal membrane health

Aids/assists repair of gastrointestinal/gut wall lining

Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

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

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

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 serious immunological diseases.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormPowder, oralRoute of AdministrationOral

Visual Identification

Active Ingredients

| Brassica oleracea var. italica sprout Powder | 87.5 mg/g |
|--|-------------|
| Equivalent: Brassica oleracea var. italica (Fresh) | 1.75 g/g |
| choline bitartrate | 62.5 mg/g |
| Curcuma longa rhizome Extract dry concentrate standardised | 21.25 mg/g |
| Equivalent: Curcuma longa (Dry) | 531.25 mg/g |
| cysteine hydrochloride | 45.31 mg/g |
| Equivalent: cysteine | 31.25 mg/g |
| glutamine | 187.5 mg/g |
| glycine | 125 mg/g |
| inositol | 50 mg/g |
| methionine | 31.25 mg/g |
| potassium sulfate | 37.5 mg/g |
| Equivalent: potassium | 16.75 mg/g |
| taurine | 125 mg/g |

Other Ingredients (Excipients)

Carrot

colloidal anhydrous silica

Flavour

Stevia rebaudiana

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