



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	344496	TriHerb
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	25/09/2020	
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 . TriHerb

Product Type	Single Medicine Product	Effective Date	24/03/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms
- Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
- Traditionally used in Western herbal medicine to nerve tonic
- Traditionally used in Western herbal medicine to nervine/support nervous system

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.
- Product presentation must not imply or refer to eating disorders.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.

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).
- Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Artemisia absinthium herb Extract dry concentrate	155.25 mg/mL
Equivalent: Artemisia absinthium (Dry)	621 mg/mL
Juglans nigra fruit hull Extract dry concentrate	47.5 mg/mL
Equivalent: Juglans nigra (Dry)	237.5 mg/mL
Syzygium aromaticum flower bud Extract dry concentrate	27 mg/mL
Equivalent: Syzygium aromaticum (Dry)	108 mg/mL

Other Ingredients (Excipients)

glycerol

lactic acid

purified water

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