



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371095	Mediherb Tribulus Forte
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	15/07/2021	
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 . Mediherb Tribulus Forte

Product Type	Single Medicine Product	Effective Date	15/07/2021
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Permitted Indications

Traditionally used in Ayurvedic medicine to body tonic

Traditionally used in Ayurvedic medicine to haemagogue/emmenagogue/promotes menstrual flow

Traditionally used in Ayurvedic medicine to improve menstrual flow

Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido

Traditionally used in Ayurvedic medicine to enhance/promote/increase urine output

Indication Requirements

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to abortifacient action.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

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Visual Identification

Active Ingredients

Tribulus terrestris herb Extract dry concentrate standardised	245.45 mg
Equivalent: Tribulus terrestris (Dry)	13.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
magnesium stearate
microcrystalline cellulose
sodium starch glycollate

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