



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300236	MediHerb Metabol Complex
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	2/03/2018	
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 Metabol Complex

Product Type	Single Medicine Product	Effective Date	8/03/2021
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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 maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to orexigenic/improve/promote healthy appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
Traditionally used in Western herbal medicine to enhance/promote healthy digestion
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Linked indication - Decrease/reduce/relieve flatulence/carminative
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Decrease/reduce/relieve abdominal cramping
Linked indication - Decrease/reduce/relieve abdominal spasm
Linked indication - Decrease/reduce/relieve nausea
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to antispasmodic/spasmodic

Indication Requirements

Product presentation must not imply or refer to eating disorders.
Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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For practitioner dispensing only.

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Cinnamomum verum stem bark Extract dry concentrate standardised	83.3 mg
Equivalent: Cinnamomum verum (Dry)	1 g
Momordica charantia fruit Extract dry concentrate	92.3 mg
Equivalent: Momordica charantia (Dry)	600 mg
Nigella sativa seed Extract dry concentrate	100 mg
Equivalent: Nigella sativa (Dry)	500 mg
Trigonella foenum-graecum seed Extract dry concentrate standardised	100 mg
Equivalent: Trigonella foenum-graecum (Dry)	10 g

Other Ingredients (Excipients)

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

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