

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: MediHerb Metabol Complex 300236

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

2/03/2018 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 Effective Date 14/04/2025 Single Medicine Product

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 abdominal cramping

Linked indication - Decrease/reduce/relieve nausea

Linked indication - Decrease/reduce/relieve abdominal bloating/distention

Linked indication - Decrease/reduce/relieve abdominal spasm

Linked indication - Decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to relieve digestive discomfort

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic

Indication Requirements

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 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 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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Produced at 18.04.2025 at 03:08:18 AEST This is not an ARTG Certificate document.



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If symptoms persist consult your healthcare practitioner (or words to that effect).

For practitioner dispensing only.

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

Additional Product information

		rmation

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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