

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Mediherb DiGest Forte 259812

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

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

8/09/2015 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 DiGest Forte

Product Type Effective Date 14/04/2025 Single Medicine Product

Permitted Indications

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 enhance/promote healthy digestion

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

Linked indication - Decrease/reduce/relieve abdominal feeling of fullness

Linked indication - Decrease/reduce/relieve nausea

Linked indication - Decrease/reduce/relieve abdominal spasm

Linked indication - Decrease/reduce/relieve abdominal cramping

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

Linked indication - Decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to relieve digestive discomfort

Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder

Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow

Traditionally used in Western herbal medicine to maintain/support bile production

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 disease in any body organ.

Product presentation must not imply or refer to eating disorders.

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

Page 1 of 2

Produced at 20.04.2025 at 03:07:13 AEST This is not an ARTG Certificate document.



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

For practitioner dispensing only.

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

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

Additional Product information

| | information | |
|--|-------------|--|
| | | |

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Artemisia absinthium herb Extract liquid 500 microlitre Equivalent: Artemisia absinthium (Dry) 100 mg Citrus reticulata fruit peel Extract dry concentrate 100 mg Equivalent: Citrus reticulata (Dry) 500 mg Gentiana lutea root Extract liquid 390 microlitre Equivalent: Gentiana lutea (Dry) 195 mg Mandarin Oil Coldpressed 12.5 mg Tanacetum parthenium leaf Extract liquid 1000 microlitre Equivalent: Tanacetum parthenium (Dry) 200 mg Zingiber officinale rhizome Extract liquid 500 microlitre Equivalent: Zingiber officinale (Dry) 250 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

croscarmellose sodium

Gentiana lutea

hypromellose

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.