



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338761	METAGENICS DIGESTEX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	2/07/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . METAGENICS DIGESTEX

Product Type	Single Medicine Product	Effective Date	2/07/2020
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to maintain/support healthy digestion
- Traditionally used in Western herbal medicine to stimulates/increases digestive gastric hydrochloric acid secretion
- Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
- Traditionally used in Western herbal medicine to maintain/support healthy gastrointestinal function
- Maintain/support healthy gastrointestinal function
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
- 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 liver tonic/Enhance liver health
- Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
- Maintain/support stomach function
- Enhance/ promote stomach health
- Traditionally used in Western herbal medicine to antiemetic/Decrease/reduce/relieve vomiting
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic

Indication Requirements



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Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to disease in any body organ.

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

Contains methyl salicylate

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

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

Visual Identification

Active Ingredients

Cinnamomum verum stem bark Extract dry concentrate	100 mg
Equivalent: Cinnamomum verum (Dry)	1 g
Filipendula ulmaria herb Extract dry concentrate	200 mg
Equivalent: Filipendula ulmaria (Dry)	2 g
Gentiana lutea root Extract dry concentrate	250 mg
Equivalent: Gentiana lutea (Dry)	1 g
Melissa officinalis leaf Extract dry concentrate	200 mg
Equivalent: Melissa officinalis (Dry)	1 g
Taraxacum officinale root Extract dry concentrate	750 mg
Equivalent: Taraxacum officinale (Dry)	3 g
Zingiber officinale rhizome Extract dry concentrate	46.88 mg
Equivalent: Zingiber officinale (Dry)	750 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
 croscarmellose sodium
 hypromellose
 macrogol 8000
 magnesium stearate
 microcrystalline cellulose
 stearic acid

Public Summary

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