Public Summary

Summary for ARTG Entry:	176365 METAGENICS LAXATONE
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	6/10/2010
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 LAXATONE

Product Type Single Medicine Product **Effective Date** 25/01/2020

Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation

Traditionally used in Western herbal medicine to stimulant laxative

Traditionally used in Western herbal medicine to maintain/support bowel regularity

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to maintain/support healthy digestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to decrease/reduce/relieve gastrointestinal pain

Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms

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

Indication Requirements

Product presentation must not refer to or imply weight loss.

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

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

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

Label statement: Drink plenty of water (or words to that effect).

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Drink plenty of water (or words to that effect).

Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product (or words to that effect).

Prolonged use may cause serious bowel problems.

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

Use in children under 12 years is not recommended.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cinnamomum cassia	**31.25 mg**
Frangula purshiana stem bark Extract dry concentrate	**100 mg**
Equivalent: Frangula purshiana (Dry)	400 mg
Matricaria chamomilla flower Extract dry concentrate	**83.33 mg**
Equivalent: Matricaria chamomilla (Dry)	500 mg
Rheum officinale root Extract dry concentrate	**25 mg**
Equivalent: Rheum officinale (Dry)	250 mg
Zingiber officinale rhizome Extract dry concentrate	**100 mg**
Equivalent: Zingiber officinale (Dry)	500 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate

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