



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--------------------------------------------------------|--------------------------|
| Summary for ARTG Entry: | 290970 | MediHerb Cascara 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 | 4/07/2017 | |
| 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 Cascara Complex

| Product Type | Single Medicine Product | Effective Date | 29/01/2021 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

Permitted Indications

- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation
- Traditionally used in Western herbal medicine to aperient/laxative
- Traditionally used in Western herbal medicine to helps reduce occurrence of constipation
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase bowel regularity
- 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 maintain/support healthy liver function

Indication Requirements

- Product presentation must not refer to or imply weight loss.
- Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.
- 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).
- Product presentation must not imply or refer to disease in any body organ.
- Label statement: If symptoms persist, talk to your health professional.
- Label statement: Drink plenty of water (or words to that effect).
- Product presentation must not imply or refer to drugs/alcohol.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

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

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

Prolonged use may cause serious bowel problems.

For practitioner dispensing only.

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).

Use in children under 12 years is not recommended.

Additional Product information

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|--------|--------------|--------------|--------------|--------------|--------------|
| Bottle | Not recorded | Not recorded | Not recorded | Not recorded | Not recorded |

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

| | |
|---------------------------------------------------------------|-----------------|
| Chamomile Oil German | 2 mg |
| Dill Seed Oil | 15 mg |
| Frangula purshiana stem bark Extract dry concentrate | 93.33 mg |
| Equivalent: Frangula purshiana (Dry) | 1.12 g |
| Rumex crispus root and rhizome Extract dry concentrate | 93.75 mg |
| Equivalent: Rumex crispus (Dry) | 375 mg |
| Taraxacum officinale root Extract dry concentrate | 93.75 mg |
| Equivalent: Taraxacum officinale (Dry) | 375 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
sodium starch glycollate

Public Summary

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