Public Summary

Summary for ARTG Entry:	172527 BLOOMS HERB-A-LAX Capsules
ARTG entry for	Medicine Listed
Sponsor	Phytologic Holdings Pty Ltd
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia
ARTG Start Date	24/06/2010
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.

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 . BLOOMS HERB-A-LAX Capsules

Product Type Single Medicine Product **Effective Date** 8/02/2021

Permitted Indications

Decrease/reduce/relieve constipation
Aperient/laxative
Helps reduce occurrence of constipation
Promote/increase bowel evacuation
Stimulant laxative
Enhance/improve/promote/increase bowel regularity
Maintain/support bowel regularity
Enhance/improve/promote/increase bowel waste elimination
Decrease/reduce/relieve bowel discomfort
Decrease/reduce/relieve flatulence/carminative
Decrease/reduce/relieve abdominal bloating/distention
Helps reduce occurrence of abdominal bloating
Decrease/reduce/relieve abdominal pain/discomfort
Relieve digestive discomfort

Indication Requirements

Product presentation must not refer to or imply weight loss.

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

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

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).

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Prolonged use may cause serious bowel problems.

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).

Use in children under 12 years is not recommended.

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

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

Anethum graveolens seed Powder	**6 mg**
Glycyrrhiza glabra root Powder	**6 mg**
Psyllium Husk Powder	**6 mg**
Rhamnus frangula stem bark Powder	**23 mg**
Senna leaf powder	**284 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica

Gelatin

magnesium stearate

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