



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	223509	BLOOMS SLIPPERY ELM BARK CAPSULES
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	16/05/2014	
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. BLOOMS SLIPPERY ELM BARK CAPSULES

Product Type	Single Medicine Product	Effective Date	26/03/2020
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Permitted Indications

Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation
Traditionally used in Western herbal medicine to promote/increase bowel evacuation
Traditionally used in Western herbal medicine to enhance/improve/promote/increase bowel regularity
Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of heartburn
Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes

Indication Requirements

Label statement: Drink plenty of water (or words to that effect).
Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.
Label statement: If symptoms persist, talk to your health professional.
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 refer to or imply weight loss.
Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (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



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

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

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (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

Slippery Elm Bark Powder

375 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

maltodextrin

silicon dioxide

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