Public Summary

Summary for ARTG Entry:	224170	BLACKMORES PERITONE
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	5/06/2014	
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 . BLACKMORES PERITONE

Product Type Single Medicine Product **Effective Date** 5/05/2020

Permitted Indications

Decrease/reduce/relieve constipation

Indication Requirements

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

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: 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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).

Prolonged use may cause serious bowel problems.

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

Additional Product information

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

Aloe ferox	**120 mg**
Equivalent: Hydroxyanthracene derivatives calculated as anhydrous barbaloin	24.6 mg
Elettaria cardamomum	**5 mg**
Frangula purshiana	**46.7 mg**
Equivalent: hydroxyanthracene derivatives calculated as cascaroside A	4.67 mg
Equivalent: Frangula purshiana	140 mg
Peppermint Oil	**300 microgram**
Equivalent: menthol	165 microgram
Zingiber officinale	**20 mg**

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
croscarmellose sodium
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
microcrystalline cellulose
purified talc
silicon dioxide
titanium dioxide