



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	224170	BLACKMORES PERITONE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Blackmores Ltd	
<b>Postal Address</b>	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
<b>ARTG Start Date</b>	5/06/2014	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/05/2020
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#### Permitted Indications

Decrease/reduce/relieve constipation

#### Indication Requirements

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

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

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

Product presentation must not refer to or imply weight loss.

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

Prolonged use may cause serious bowel problems.

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).

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

Use in children under 12 years is not recommended.

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

#### Additional Product information

Public Summary



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**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**

<b>Aloe ferox leaf inner juice Powder</b>	<b>120 mg</b>
<b>Elettaria cardamomum fruit Powder</b>	<b>5 mg</b>
<b>Frangula purshiana stem bark Extract dry concentrate</b>	<b>46.7 mg</b>
Equivalent: Frangula purshiana (Dry)	140 mg
<b>Peppermint Oil</b>	<b>300 microgram</b>
<b>Zingiber officinale root Powder</b>	<b>20 mg</b>

**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

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