



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	409907	EnteroLax
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio-Practica Pty Ltd	
<b>Postal Address</b>	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	1/06/2023	
<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.

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 . EnteroLax

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/06/2023
---------------------	-------------------------	-----------------------	-----------

### Permitted Indications

Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier  
Traditionally used in Western herbal medicine to aids/assists natural body cleansing/detoxification processes  
Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products  
Traditionally used in Chinese medicine to remove Heat toxin  
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing  
Traditionally used in Chinese medicine to maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of haemorrhoids  
Traditionally used in Western herbal medicine to bowel Tonic  
Decrease/reduce/relieve constipation  
Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation  
Aperient/laxative  
Traditionally used in Western herbal medicine to aperient/laxative  
Stimulant laxative  
Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)  
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative  
Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal pain/discomfort  
Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal spasm  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms  
Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder  
Maintain/support gallbladder function  
Traditionally used in Western herbal medicine to maintain/support gallbladder function  
Traditionally used in Western herbal medicine to liver tonic/Enhance liver health  
Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic  
Maintain/support healthy liver function



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

Traditionally used in Western herbal medicine to maintain/support healthy liver function  
Traditionally used in Western herbal medicine to antiemetic/Decrease/reduce/relieve vomiting  
Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea

#### Indication Requirements

Label statement: Drink plenty of water (or words to that effect).  
Label statement: If symptoms persist, talk to your health professional.  
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.  
Product presentation must not imply or refer to disease in any body organ.  
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
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.  
Product presentation must not imply or refer to drugs/alcohol.  
  
Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.  
If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

#### 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).  
Prolonged use may cause serious bowel problems.  
Use in children under 12 years is not recommended.

#### 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

<b>Frangula purshiana stem bark Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Frangula purshiana (Dry)	500 mg
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>192.31 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	2.5 g
<b>Peppermint Oil</b>	<b>30 mg</b>
<b>Taraxacum officinale root Extract dry concentrate</b>	<b>400 mg</b>
Equivalent: Taraxacum officinale (Dry)	2 g

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

hypromellose  
macrogol 400  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
povidone

---

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary