



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323852	Bowel Cleanse
ARTG entry for	Medicine Listed	
Sponsor	Nutrition Care Pharmaceuticals Pty Ltd	
Postal Address	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
ARTG Start Date	20/09/2019	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Bowel Cleanse

Product Type	Single Medicine Product	Effective Date	20/09/2019
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Traditionally used in Chinese medicine to moisten the intestines
Maintain/support general health and wellbeing
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support blood capillary health
Maintain/support blood vessel health
Traditionally used in Chinese medicine to open/relax bowels
Traditionally used in Chinese medicine to decrease/reduce/relieve constipation
Traditionally used in Chinese medicine to aperient/laxative
Maintain/support immune system health
Maintain/support healthy immune system function
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support skin health
Maintain/support wound healing

Indication Requirements

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



Australian Government
Department of Health
 Therapeutic Goods Administration

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

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (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 serious immunological diseases.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not refer to or imply weight loss.

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.

Product presentation must not imply or refer to disease in any body organ.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Use in children under 12 years is not recommended.

If symptoms persist consult your healthcare practitioner (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).

Prolonged use may cause serious bowel problems.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	62.5 mg
d-alpha-tocopheryl acid succinate	750 microgram
inulin	250 mg
Prunus domestica fruit Extract dry concentrate	62.5 microgram
Equivalent: Prunus domestica (Fresh)	250 microgram
Senna tora seed Extract dry concentrate	75 mg
Equivalent: Senna tora (Dry)	1.69 g

Other Ingredients (Excipients)

- citric acid**
- colloidal anhydrous silica**
- ethylcellulose**
- glucose monohydrate**
- hypromellose**
- isomalt**
- magnesium stearate**

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

maltodextrin

Peppermint Oil

povidone

sucralose

© 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