Public Summary

Summary for ARTG Entry:	106618	Nature's Sunshine Bowel Calm

ARTG entry for	Medicine Listed
Sponsor	Nature's Sunshine Products of Australia Pty Ltd
Postal Address	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia
ARTG Start Date	30/07/2004
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 . Nature's Sunshine Bowel Calm

Product Type	Single Medicine Product	**Effective Date**	14/08/2019

Permitted Indications

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation

Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation

Traditionally used in Western herbal medicine to aperient/laxative

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder

Indication Requirements

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

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

Product presentation must not refer to or imply weight loss.

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

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

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 gastro oesophageal reflux disease.

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).

Drink plenty of water (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.

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

Berberis aquifolium root and rhizome Powder	**98 mg**
Dioscorea villosa root Powder	**30 mg**
Foeniculum vulgare seed Powder	**60 mg**
Mentha X piperita leaf Powder	**30 mg**
Nepeta cataria leaf Powder	**22 mg**
Viburnum opulus stem bark Powder	**64 mg**
Zingiber officinale rhizome Powder	**71 mg**

Other Ingredients (Excipients)

Gelatin
glacial acetic acid
potable water
silicon dioxide
sodium lauryl sulfate

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