



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

## Public Summary

<b>Summary for ARTG Entry:</b>	383219	Nature's Sunshine Lower Bowel Stimulant
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Nature's Sunshine Products of Australia Pty Ltd	
<b>Postal Address</b>	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia	
<b>ARTG Start Date</b>	31/01/2022	
<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 . Nature's Sunshine Lower Bowel Stimulant

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	31/01/2022
---------------------	-------------------------	-----------------------	------------

### Permitted Indications

- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation
- Traditionally used in Western herbal medicine to stimulant laxative
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase bowel regularity
- Traditionally used in Western herbal medicine to maintain/support bowel regularity
- Traditionally used in Western herbal medicine to softens stool to ease bowel motions
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bowel discomfort
- Traditionally used in Western herbal medicine to helps enhance/promote healthy digestive system function

### Indication Requirements

- 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).
- Label statement: Drink plenty of water (or words to that effect).
- Product presentation must not refer to or imply weight loss.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

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

Public Summary



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

healthcare professional before taking this product (or words to that effect).

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

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** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Berberis aquifolium root and rhizome Powder</b>	<b>10.9 mg</b>
<b>Capsicum annuum fruit Powder</b>	<b>21.8 mg</b>
<b>Elymus repens rhizome Powder</b>	<b>10.9 mg</b>
<b>Frangula purshiana stem bark Powder</b>	<b>196.1 mg</b>
<b>Liquorice Powder</b>	<b>65.4 mg</b>
<b>Rhamnus frangula stem bark Powder</b>	<b>76.3 mg</b>
<b>Rheum officinale root Powder</b>	<b>10.9 mg</b>
<b>Trifolium pratense flower Powder</b>	<b>10.9 mg</b>
<b>Zingiber officinale rhizome Powder</b>	<b>21.8 mg</b>

**Other Ingredients (Excipients)**

hypromellose

purified water

silicon dioxide

sorbitol

© 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