



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

## Public Summary

<b>Summary for ARTG Entry:</b>	158420	Agiolax granules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SFI Australasia	
<b>Postal Address</b>	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
<b>ARTG Start Date</b>	12/01/2009	
<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 . Agiolax granules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/12/2021
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### Permitted Indications

Maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation  
Decrease/reduce/relieve constipation  
Traditionally used in Western herbal medicine to aperient/laxative  
Aperient/laxative  
Helps reduce occurrence of constipation  
Increase bowel movements by increasing stool bulk  
Maintain/support bowel regularity by increasing stool bulk  
Traditionally used in Western herbal medicine to promote/increase bowel evacuation  
Promote/increase bowel evacuation  
Stimulant laxative  
Traditionally used in Western herbal medicine to stimulant laxative  
Maintain/support bowel regularity  
Traditionally used in Western herbal medicine to enhance/improve/promote/increase bowel waste elimination  
Maintain/support healthy bowel/colon function

### Indication Requirements

Label statement: Drink plenty of water (or words to that effect).  
Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.  
Label statement: If symptoms persist, talk to your health professional.  
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



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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).

(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].

Prolonged use may cause serious bowel problems.

Use in children under 12 years is not recommended.

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

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

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Granules

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

Ispaghula Husk Dry	22 mg/g
Psyllium Seed Dry	520 mg/g
Senna fruit tinnevelly dry	100 mg/g

**Other Ingredients (Excipients)**

Acacia

Caraway Oil

hard paraffin

iron oxide black

iron oxide red

iron oxide yellow

liquid paraffin

Peppermint Oil

purified talc

Sage Oil Spanish

sucrose

Public Summary

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