



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	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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