Public Summary

Summary for ARTG Entry:	65611 Agiofibe granules
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	31/07/1998
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 . Agiofibe granules

Product Type Single Medicine Product **Effective Date** 2/11/2021

Permitted Indications

Maintain/support general health and wellbeing

Decrease/reduce/relieve constipation

Increase bowel movements by increasing stool bulk

Maintain/support bowel regularity by increasing stool bulk

Maintain/support bowel regularity

Decrease/reduce/relieve bowel discomfort

Maintain/support healthy bowel/colon function

Indication Requirements

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

Label statement: Drink plenty of water (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 refer to or imply weight loss.

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

(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].

Additional Product information

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**
Plantago ovata seed Dry	**650 mg/g**

Other Ingredients (Excipients)

Acacia
Caraway Oil
hard paraffin
iron oxide red
iron oxide yellow
liquid paraffin
Peppermint Oil
purified talc
Sage Oil Spanish
sucrose
titanium dioxide