New Zealand Datasheet

1 PRODUCT NAME
NORMAFIBE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sterculia 62% w/w

3 PHARMACEUTICAL FORM
NORMAFIBE are white irregular shaped granules with a sweet taste.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
The treatment of constipation, particularly simple or idiopathic constipation and constipation during pregnancy.

Management of colostomies and ileostomies.

The 'High Residue Diet' management of diverticular disease of the colon and other conditions requiring a high fibre regimen.

The initiation and maintenance of bowel action after rectal and anal surgery.

Administration after ingestion of sharp foreign bodies to provide a coating and reduce the possibility of intestinal damage during transit.

4.2 Dose and method of administration
Adults: 1 or 2 sachets or 1-2 heaped 5ml spoonfuls, once or twice daily after meals.

Elderly: As per the adult dose.

Children: (6-12 years): one half the above amount.
NORMAFIBE is not recommended for children under 6 years of age.

The granules should be placed dry on the tongue and without chewing or crushing, swallowed immediately with plenty of water or a cool drink. Prior to drinking they may also be sprinkled onto and taken with soft food such as yoghurt, and then immediately drinking plenty of water or a cool drink.

4.3 Contraindications
Intestinal obstruction, faecal impaction, and total atony of the colon.

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Not to be taken immediately before going to bed or in a recumbent position especially in the elderly. Adequate fluid should be maintained. Caution should be exercised in cases of ulcerative colitis. Not to be taken for more than 4 days if there has been no movement of the bowels. Take with plenty of water to reduce the risk of oesophageal obstruction.

Patients with rare hereditary problems of fructose intolerance, glucose–galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

It is not unusual for stool to appear paler in colour than normal as a result of local contact with sterculia. This does not indicate anything untoward.

4.5 Interaction with other medicines and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy

NORMAFIBE may be recommended during pregnancy.

Breast feeding

NORMAFIBE may be recommended lactation.

4.7 Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

4.8 Undesirable effects

System Order Class	Adverse Drug Reaction
Immune system disorders	Allergic reactions
Gastrointestinal disorders	Oesophageal obstruction, intestinal obstruction or impaction, abdominal distension, flatulence, diarrhoea, nausea, abdominal pain

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Intestinal obstruction is possible in overdosage particularly in combination with inadequate fluid intake. Management is as for intestinal obstruction from other causes. If there is profound diarrhoea, dehydration and electrolyte depletion may occur.

In case of accidental overdosage, symptomatic treatments and supportive care are suggested. For information on the management of overdose, contact the National Poisons Centre on 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bulk-forming laxatives, ATC Code: A06AC

Actions

Sterculia acts in the colon by forming a soft bulky stool and inducing a laxative effect.

5.2 Pharmacokinetic properties

Sterculia is not absorbed or digested in the gastrointestinal tract and its laxative action is normally effective within 12 hours of oral administration.

5.3 Preclinical safety data

There is no evidence that Sterculia has a significant systemic toxicity potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium bicarbonate, sucrose, talc, paraffin wax, titanium dioxide, vanillin.

This medicine contains approximately 17mg sodium in each 5 mL spoon of NORMAFIBE granules that is to say essentially ‘sodium-free’. The WHO recommended maximum daily intake of sodium for an adult is 2 grams.

6.2 Incompatibilities

None are known.

6.3 Shelf life

2 years (24 months).

6.4 Special precautions for storage

Store in a dry place below 25ºC.

6.5 Nature and contents of container

Sachet containing 7 g of white granules in a carton of 7 sachets used as a sample.

Lined box of 500 g of white granules.

6.6 Special precautions for disposal

No special precautions required.

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Sponsor:
CARSL Consulting
PO Box 766
Hastings
Ph (06) 875 0979

for Norgine Pty Limited

Distributor:
Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
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9 DATE OF FIRST APPROVAL

31 December 1969

10 DATE OF REVISION OF THE TEXT

17 September 2020

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
6.1	Text added: “This medicine contains approximately 17mg sodium in each 5 mL spoon of NORMAFIBE granules that is to say essentially ‘sodium-free’. The WHO recommended maximum daily intake of sodium for an adult is 2 grams.”