

New Zealand Datasheet

Name of Medicine

NORMACOL

Presentation

NORMACOL is a white irregular shaped granules with a sweet taste containing Sterculia 62% w/w.

Uses

Actions

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

Pharmacokinetics

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

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.

Dosage and 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.

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.

Contraindications

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

Known hypersensitivity to any of the ingredients

Warnings and Precautions

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.

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.

Use in Pregnancy and Lactation

NORMACOL may be recommended during pregnancy or lactation.

Effects on Ability to Drive and Use Machines

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

Adverse Effects

Immune system disorders: allergic reactions

Gastrointestinal disorders: Intestinal/colonic obstruction or impaction, flatulence.

Occasionally mild abdominal distension may occur.

Oesophageal obstruction is possible if the product is taken in overdose or if it is not adequately washed down with fluid.

Interactions

None known.

Overdosage

Intestinal obstruction is possible in overdose particularly in combination with inadequate fluid intake. Management is as for intestinal obstruction from other causes.

Pharmaceutical Precautions

Store in a dry place below 25°C.

Medical Classification

General Sale Medicine.

Package Quantities

Sachet containing 7 g of white granules in boxes of 30 or 60 sachets.

Lined box of 500 g of white granules.

Further Information

Preclinical safety data

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

Excipients

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

Incompatibilities

None are known.

Name and Address

Sponsor:

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3 November 2009

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