1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

NORMACOL 6,2 g per 10 g granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g of NORMACOL granules contains 6,2 g of sterculia.

Contains sugar: Sucrose 2,4593 g

NORMACOL is gluten free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules.

White irregular shaped granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

NORMACOL is indicated in adults and children over the age of 6 years for:

- The treatment of constipation, particularly simple or idiopathic constipation and constipation during pregnancy and lactation.
- Management of colostomies and ileostomies.
- The ‘High Residue Diet’ management of diverticular disease of the colon and other conditions requiring a high fibre regimen.

- Relief of symptoms of irritable bowel syndrome.
- 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 Posology and method of administration

Posology

Adolescents and adults (including the elderly):

Take one to two heaped medicine measures, once or twice daily.

Take after meals.

NORMACOL generally produces a bowel movement in 12 to 72 hours.

Special populations

Elderly

See Posology above.

Renal impairment

The safety and efficacy of NORMACOL in patients with renal impairment has not been established.

Hepatic impairment

The safety and efficacy of NORMACOL in patients with hepatic impairment has not been established.

Paediatric population

Children (6 to 12 years):

One half the adult dose or as directed by the medical practitioner or pharmacist.

NORMACOL is not recommended for children under the age of 6 years (see section 4.3).

Method of administration

NORMACOL granules should be placed dry on the tongue, in small quantities if necessary, and, without chewing or crushing, swallowed immediately with plenty of water or a cool drink. The granules may also be sprinkled onto and taken with soft food such as yoghurt and then immediately drink plenty of water or a cool drink.

4.3 Contraindications

NORMACOL is contraindicated in:

- Patients with hypersensitivity to sterculia or to any of the excipients in NORMACOL (see section 6.1).
- Patients with intestinal obstruction.
- Patients with faecal impaction, colonic atony and other conditions where the administration of an intestinal evacuant is inadvisable.
- Children under the age of 6 years.

4.4 Special warnings and precautions for use

NORMACOL should not be taken immediately before going to bed or in a recumbent position especially in the elderly.

Possible fluid and electrolyte depletion in association with diarrhoea.

Patients should take NORMACOL with plenty of water to reduce the risk of faecal impaction, large bowel obstruction and oesophageal obstruction. Adequate fluid intake should be maintained. NORMACOL should not be used in the presence of abdominal pain, nausea and vomiting. NORMACOL should not be used for a period longer than one week, unless directed by a doctor.

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

If patients notice a sudden change in bowel habits that has persisted for a period of longer than two weeks, they should consult a doctor before using NORMACOL. Frequent and prolonged use of NORMACOL may result in dependence on laxatives and loss of normal bowel function.

Rectal bleeding or failure to have a bowel movement after the use of a laxative, such as NORMACOL, may indicate a serious condition. Patients should discontinue the use of NORMACOL and consult a doctor. NORMACOL should not be taken for more than 4 days if there has been no movement of the bowels.

Caution should be exercised in cases of ulcerative colitis. Obstruction is possible if NORMACOL is taken in overdose or is not adequately washed down with fluids.

Excipients

Sucrose

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

Sodium

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

4.5 Interaction with other medicines and other forms of interaction

NORMACOL lowers the transit time through the gut and could interfere with the absorption of other medicines.

4.6 Fertility, pregnancy and lactation

Safe for use in pregnancy and lactation.

Fertility

There is no fertility data.

4.7 Effects on ability to drive and use machines

NORMACOL has none or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a) Tabulated list of adverse reactions

System organ class	Less frequent
Immune system disorders	Allergic reactions
Gastrointestinal disorders	Oesophageal obstruction, intestinal/colonic obstruction or impaction, abdominal distension, flatulence, diarrhoea, nausea, abdominal pain
Skin and subcutaneous tissue disorders	Urticaria

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 providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9 Overdose

Symptoms

Intestinal obstruction is possible in overdosage particularly in combination with inadequate fluid intake.

Management

Management is as for intestinal obstruction from other causes. If there is profound diarrhoea, dehydration and electrolyte depletion may occur.

Treatment is supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 11.5 Medicines acting on the gastrointestinal tract: Laxatives

Pharmacotherapeutic group: Laxatives

ATC code: A06AC03

Mechanism of action

NORMACOL is a laxative that contains sterculia. Sterculia is a high molecular mass, polysaccharide gum. Sterculia is a bulking medicine that stimulates the motility of the colon by increasing faecal volume and reduces intraluminal recto-sigmoid pressure.

5.2 Pharmacokinetic properties

Absorption

Sterculia is not absorbed in the gastrointestinal tract.

Elimination

Sterculia is eliminated via the faeces.

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

Paraffin hard, sodium hydrogen carbonate (for pH adjustment), sucrose, talc, titanium dioxide, vanillin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a dry place at or below 25 °C.

Keep in original packaging until required for use.

6.5 Nature and contents of container

500 g is packed in a laminated, Kraft paper and low density polyethylene liner bag which is glued into an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8 REGISTRATION NUMBER

E1974 (Act 101 of 1965)

9 DATE OF FIRST AUTHORISATION

Date of registration: Old Medicine

10 DATE OF REVISION OF TEXT

10 June 2022

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

Botswana: BOT0801456 S4

Namibia: NS0 05/11.5/0441

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