# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Normacol 62% w/w Granules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of NORMACOL Granules contains 0.62g of Sterculia BP (62% w/w).
Each sachet contains 4.34g of Sterculia BP.
Excipient(s) with know effect:
Contains 1.7g of sucrose and 28.7mg of sodium per 7g sachet
Contains 1.0g of sucrose and 16.8mg of sodium per 5ml spoonful
For a full list of excipients, see 6.1

## 3 PHARMACEUTICAL FORM

Granules
White irregular shaped granules.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

The treatment of constipation (including 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.

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

***Adults:*** 1 or 2 sachets or 1-2 heaped 5ml spoonfuls, once or twice daily after meals.
***Older People:***
As adult dose.
Paediatric population
***Children (6-12 years):*** one half the above amount or as directed by the physician.
NORMACOL® 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.

### 4.3 Contraindications

Intestinal obstruction, faecal impaction, and colonic atony.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

Known hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

Adequate fluid intake should be maintained.

Caution should be exercised in cases of ulcerative colitis.
Patients should be advised:

- of possible fluid and electrolyte depletion in association with diarrhoea.
- to take with plenty of water to reduce the risk of oesophageal obstruction.
- to take plenty of water and to maintain an adequate fluid intake.
- to avoid taking NORMACOL immediately before going to bed or in a recumbent position (especially if they are elderly).
- to suspend treatment if bowel movements do not occur within four days.It is not unusual for stools to appear paler in colour than normal as a result of local contact with sterculia. This does not indicate anything untoward.

This medicinal product contains 28.7 mg sodium per 7g sachet or 16.8mg of sodium per 5ml spoonful, equivalent to 1.5 % or 0.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

**4.5 Interaction with other medicinal products and other forms of interactions**

None known.

**4.6 Fertility, pregnancy and lactation**

NORMACOL may be used during pregnancy or lactation.

**4.7 Effects on ability to drive and use machines**

NORMACOL has no influence on the ability to drive or 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 medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions
via HPRA Pharmacovigilance Website: www.hpra.ie.

**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. Oesophageal obstruction is possible if the product is taken in overdosage.
If there is profound diarrhoea, dehydration and electrolyte depletion may occur.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

NORMACOL is a laxative which contains sterculia. Sterculia is a bulking agent which stimulates the motility of the colon by increasing faecal volume, and reduces intraluminal recto-sigmoid pressure. 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

Sucrose
Talc
Sodium hydrogen carbonate
Hard paraffin
Titanium dioxide (E171)
Vanillin

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Sachet and carton: 2 years.

### 6.4 Special precautions for storage

Sachet: Do not store above 25°C. Store in the original package in a dry place.
Carton: Do not store above 25°C. Store in the original package in a dry place. Keep the carton tightly closed.

### 6.5 Nature and contents of container

Sachet: Laminate consisting of 4 layers of low density polyethylene; aluminium; low density polyethylene and paper.

Each sachet contains 7g of white granules supplied in boxes of 2,7 or 60 sachets.

Carton lining: laminate consisting of 4 layers of low density polyethylene; aluminium; low density polyethylene and paper.

Lined carton of 500g of white granules.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Norgine B.V.
Antonio Vivaldistraat 150
1083 HP Amsterdam
Netherlands

## 8 MARKETING AUTHORISATION NUMBER

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 September 1984

Date of last renewal: 25 September 2009

## 10 DATE OF REVISION OF THE TEXT

January 2021