Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Normacol Plus Granules Sterculia 62% w/w Frangula 8% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Normacol Plus Granules contains 0.62g (62% w/w) of Sterculia and 0.08g (8% w/w) of Frangula.

Each sachet contains 4.34g of Sterculia and 0.56g of Frangula.

Excipients: contains sucrose 25% w/w, sodium hydrogen carbonate 1.5% w/w and sunset yellow FCF (E110).

For a full list of excipients, see section 6.1.
Also contains up to to 28.7mg of sodium per 7g sachet.

3 PHARMACEUTICAL FORM

Granules.
Brown irregular shaped granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The treatment of constipation and diverticulosis, particularly hypertonic or slow transit constipation, resistant to bulk alone.

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

4.2 Posology and method of administration

Adults (including the elderly) and children aged 12 years and over:

Sachets

One sachet (equivalent to 7g of Normacol Plus) or two sachets (equivalent to 14g of Normacol Plus) per day, after meals.

Or

Granules

One heaped 5ml spoonful (equivalent to 3.5g of Normacol Plus) or two heaped 5ml spoonfuls (equivalent to 7g of Normacol Plus) to be taken once or twice a day, after meals.

The recommended dose of this herbal preparation is equivalent to 10 – 30 mg hydroxyanthracene derivatives, calculated as glucofrangulin A.

Paediatric Population

Normacol Plus is not recommended for use in children under 12 years of age (see section 4.3).

Method of administration

The granules should be placed dry on the tongue and, without chewing or crushing, swallowed immediately with plenty of water or a cool drink, until the patient feels the granules have been completely washed down. 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. As with other laxatives, use for more than 1 – 2 weeks requires medical supervision.

4.3 Contraindications

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

Intestinal obstruction.

Faecal impaction and colonic atony.

Pregnancy and lactation.

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

Children under 12 years of age.

4.4 Special warnings and precautions for use

Adequate fluid intake should be maintained.

Caution should be exercised in the use of NORMACOL Plus in cases of ulcerative colitis.

Patients should be advised to:

- Take NORMACOL Plus with plenty of water to reduce the risk of oesophageal obstruction.
- Avoid taking NORMACOL Plus immediately before going to bed or in a recumbent position (especially if they are elderly)
- Suspend treatment if bowel movements do not occur within four days.

Prolonged and excessive use of stimulant laxatives can cause dependence and loss of normal bowel function. Possible fluid and electrolyte depletion in association with diarrhoea.

Laxatives containing frangula bark should not be taken by patients suffering from faecal impaction and undiagnosed, acute or persistent gastrointestinal complaints, e.g. abdominal pain, nausea and vomiting unless advised by a doctor because these symptoms can be signs of potential or existing intestinal blockage (ileus).

This medicianl product contains 28.7mg of sodium per 7g sachet, equivalent to 1.5% of the WHO recommended maximum daily intake of 2g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interactions

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, or other medicinal products that induce reversion to sinus rhythm (e.g. quinidine) or with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products inducing hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

4.6 Fertility, pregnancy and lactation

Pregnancy:
There are no data from the use of sterculia and frangula in pregnant women. However, studies in animals have shown reproductive toxicity (see section 5.3). Therefore, Normacol Plus is contraindicated during pregnancy (see section 4.3).

Breastfeeding:
There is no evidence that sterculia is excreted in human milk. It is unknown whether frangula or its metabolites are excreted in human milk. Available toxicological data in animals have shown possible excretion of metabolites of anthranoid metabolites in milk (for details see 5.3). A risk to the suckling child cannot be excluded. Normacol Plus is therefore contraindicated during breastfeeding (see section 4.3).

Normacol (Sterculia alone) is available if required in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Normacol Plus has no influence on the ability to drive or use machines.

4.8 Undesirable effects

The following CIOMS frequency classification according to the MedDRA database should be used where applicable: Very common ≥ 1/10; Common ≥ 1/100, <1/10; Uncommon ≥ 1/1,000, <1/100; Rare ≥ 1/10,000, <1/1,000; Very rare <1/10,000; Unknown (cannot be estimated from the available data).

System Organ Class	Adverse Drug Reactions
Immune system disorders	Unknown – Allergic reactions
Gastrointestinal disorders	Unknown – Oesophageal obstruction, intestinal obstruction or impaction, abdominal distension, flatulence, diarrhoea, nausea, abdominal pain, melanosis coli

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

Sterculia acts in the colon by forming a soft bulky stool and inducing a laxative effect. Frangula acts as a mild peristaltic stimulant and aids the evacuation of the softened faecal mass.

5.2 Pharmacokinetic properties

Sterculia is not absorbed in the gastrointestinal tract; Frangula acts locally on the wall of the intestinal tract. The laxative action of Normacol Plus is normally effective within 12 hours of oral administration.

5.3 Preclinical safety data

No pre-clinical data are available for frangula. Although no teratogenic effects have been reported, pre-clinical data suggest a possible genotoxic risk for several anthranoids. There is also evidence to suggest that products of this class may cross the placenta and small amounts of metabolites may be excreted in breast milk.

There is no evidence that sterculia has a significant systemic toxicity potential, based on repeated dose toxicity, reproductive toxicity and genotoxicity studies. Pre-clinical carcinogenicity studies with sterculia are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Talc
Sodium Hydrogen Carbonate
Hard paraffin
Peppermint flavouring
Indigo carmine (E132)
Erythrosine (E127)
Sunset yellow FCF (E110)
Sodium chloride

This medicine contains approximately 16mg sodium in each 5mL spoon of Normacol Plus 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

Not applicable

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 order to protect from moisture.

Carton: Do not store above 25°C. Store in the original package. Keep the carton tightly closed in order to protect from moisture.

6.5 Nature and contents of container

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

Each sachet contains 7g of brown granules supplied in boxes of 2, 7, 10, 30 or 60 sachets.

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

Lined carton of 200g or 500g of brown 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

PA1336/008/001

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

November 2021