

AUSTRALIAN PRODUCT INFORMATION – NORMACOL® PLUS (ACTIVE STERCULIA, RHAMNUS FRANGULA) ORAL GRANULES

1 NAME OF THE MEDICINE

Sterculia and Rhamnus Frangula (frangula) bark powder.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sucrose coated granules containing Sterculia 62% and Frangula bark powder 8%.

Contains sucrose 25% w/w.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Brown sugar-coated granules.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Treatment of constipation, particularly hypotonic or slow transit constipation resistant to bulk alone. The initiating and maintenance of bowel action after rectal surgery and haemorrhoidectomy.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults (including the elderly)

One to two heaped 5 mL spoonfuls once or twice daily after meals.

Normacol Plus is not recommended for children under 12 years of age.

The granules should be placed dry on the tongue (in small quantities if necessary) and, without chewing or crushing, swallowed immediately with plenty of liquid (water or cool drink). 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 stimulant laxatives, use for more than 1-2 weeks requires medical supervision.

4.3 CONTRAINDICATIONS

- Intestinal obstruction
- Faecal impaction.
- Total atony of the colon.
- Hypersensitivity to the active substances or to any of the excipients.
- Pregnancy and lactation.
- Children under 12 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Precautions

Not to be taken immediately before going to bed or in a recumbent position, especially in the elderly. Adequate fluid intake should be maintained. Caution should be exercised in cases of ulcerative colitis. Possible fluid and electrolyte depletion in association with diarrhoea.

Prolonged and excessive use of stimulant laxatives can cause dependence and loss of normal bowel function.

Take with plenty of water to reduce the risk of oesophageal obstruction.

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).

Use in the elderly

Not to be taken immediately before going to bed or in a recumbent position.

Paediatric use

Not to be used in children under 12 years of age.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES 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

Effects on fertility

No data available.

Use in pregnancy

Pregnancy Category – None assigned.

No teratogenic effects have been reported with Normacol Plus.

There are no data from the use of Sterculia and Frangula bark powder in pregnant women. Therefore NORMACOL Plus is contraindicated during pregnancy.

Use in lactation.

There is no evidence that Sterculia is excreted in human milk.

It is unknown whether Frangula bark powder or its metabolites are excreted in human milk. A risk to

the breast feeding child cannot be excluded. Therefore NORMACOL Plus is contraindicated during breastfeeding.

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 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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

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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Intestinal obstruction is possible if the product is taken in overdose or is not adequately washed down with fluid. Management of overdose is as for intestinal obstruction from other causes. If there is profound diarrhoea, dehydration and electrolyte depletion may occur.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Sterculia is a vegetable gum that absorbs up to 60 times its own volume of water i.e. six times as much as methylcellulose or psyllium. Sterculia is a bulk-forming laxative.

Frangula bark powder is a peristaltic stimulant.

Clinical trials

No clinical trial data are available for this product.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No Information available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Normacol Plus contains the following excipients: sucrose (25% w/w), purified talc, sodium bicarbonate, hard paraffin, peppermint flavour (Arome Peppermint Extra H 9979) and brown dye, containing erythrosine, indigo carmine, sunset yellow FCF, and sodium chloride.

Each 7 grams of Normacol Plus (equivalent to one heaped 5 mL teaspoonful of granules) contains 1.72 g of available carbohydrate equivalent to 6.75 Kcal and approximately 4.5 g Sterculia and 0.5 g Frangula bark powder.

Normacol Plus does not contain any gluten.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

Cartons of 200 g and 500 g.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Not available.

CAS number

Sterculia 9000-36-6

Frangula bark powder – not available

7 MEDICINE SCHEDULE (POISONS STANDARD)

Nil

8 SPONSOR

Norgine Pty Ltd

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9 DATE OF FIRST APPROVAL

2 October 1991

10 DATE OF REVISION

13 August 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
ALL	Product information in new format
1.0	Inserted AAN for frangula – Rhamnus Frangula
4.2	Text regarding use in Children (6-12 years old) deleted. Medical supervision statement added
4.3	Contraindication for children under 12 years of age added.
4.4	Cautionary statements updated/added
4.5	Interaction statement added.
4.8	CIOMS frequency classifications added.
8	Updated sponsor address

Normacol® is a registered trademark of the Norgine group of companies.