New Zealand Datasheet

1 PRODUCT NAME
NORMACOL® PLUS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
The active substances are sterculia 62% w/w and Rhamnus Frangula (Frangula) 8% w/w.

Excipients: Contains sucrose 25% w/w, sodium bicarbonate 1.5% w/w and sunset yellow FCF (E110).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Oral 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 and children over 12 years (including the elderly)
One to two 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
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. Take with plenty of water to reduce the risk of oesophageal obstruction.

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

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).

4.5 Interaction with other medicines and other forms of interaction

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 bark powder in pregnant women. Therefore, NORMACOL Plus is contraindicated during pregnancy.

Breast feeding

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.

Fertility

In animals there are no effects of sennosides on male or female fertility.

4.7 Effects on ability to drive and use machines

There is no known effect on the ability to drive and 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 Order Class	Adverse Drug Reaction
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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Intestinal obstruction is possible if the product is taken in overdosage 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.

In case of accidental overdosage, symptomatic treatments and supportive care are suggested. For information on the management of overdose, contact the National Poisons Centre on 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bulk-forming laxatives, ATC Code: A06AC53

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.

5.2 Pharmacokinetic properties

Sterculia is not absorbed in the gastrointestinal tract; it is eliminated in the faeces. Frangula acts locally on the wall of the intestinal tract, although there is some systemic absorption. The laxative action of NORMACOL Plus is normally effective within 12 – 72 hours of oral administration.

5.3 Preclinical safety data

There is no evidence that sterculia has a significant systemic toxicity potential based on repeated dose toxicity, reproductive toxicity and genotoxicity studies.

No general or reproduction toxicology data exist for frangula. However, repeat dose studies with related material (anthranoid compounds) showed that these are well tolerated.

Available toxicological data in animals have shown possible excretion of anthranoid metabolites in milk.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose (25% w/w), purified talc, sodium bicarbonate, hard paraffin, peppermint flavour (Arome Peppermint Extra H 9979), erythrosine, indigo carmine, sunset yellow FCF.

6.2 Incompatibilities

None are known.

6.3 Shelf life

24 months

6.4 Special precautions for storage
Store in a dry place below 25ºC.

6.5 Nature and contents of container
Lined box of 200 g or 500 g.

6.6 Special precautions for disposal
No special precautions required.

7 MEDICINE SCHEDULE
General Sale Medicine.

8 SPONSOR
Sponsor:
CARSL Consulting
PO Box 766
Hastings
Ph (06) 875 0979

For Norgine Pty Limited

Distributor:
Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
PO Box 62-027
Mt Wellington
Auckland
Telephone: (09) 918 5100
Fax: (09) 918 5101

9 DATE OF FIRST APPROVAL
31 December 1969

10 DATE OF REVISION OF THE TEXT
27 February 2019 CCDS 4.0

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Updated to SPC format
2	Included excipient details
4.2	Removal of dosage for children under 12 years.
4.4	Warning added regarding prolonged and excessive use of. Warning added regarding patients suffering from faecal impaction and undiagnosed, acute or persistent gastrointestinal complaints.
4.5	Effects of hypokalaemia added.
4.7	Fertility section added
4.8	Adverse event frequencies added. Reporting of adverse reactions added.
4.9	National Poisons Centre contact added.
5.1	Pharmacotherapeutic group added
5.2	Section added
5.3	Section added
8	Sponsor address updated