

NORMACOL PLUS Product Information

PRODUCT NAME

NORMACOL[®] PLUS Granules

ACTIVE INGREDIENTS

Sterculia, Frangula bark powder

PRODUCT DESCRIPTION

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

Normacol Plus contains the following excipients: sucrose, purified talc, sodium bicarbonate, hard paraffin, peppermint flavour (Arome Peppermint Extra H 9979), erythrosine, indigo carmine, sunset yellow FCF.

PHARMACOLOGY

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.

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.

CONTRAINDICATIONS

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

PRECAUTIONS

Not to be taken immediately before retiring or in 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.

Use in pregnancy:

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.

ADVERSE REACTIONS

Allergic reactions. Oesophageal obstruction, abdominal cramp, abdominal distension. Intestinal obstruction is possible if the product is taken in overdosage or is not adequately washed down with fluid.

DOSAGE AND ADMINISTRATION

Adults (including the elderly)

1-2 heaped teaspoonfuls once or twice daily after meals.

Children (6-12 years old)

One half of the above amount.

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). Children may prefer to take the granules mixed with jam, honey or ice cream.

OVERDOSAGE

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.

PRESENTATION

Cartons of 100 g, 200 g and 500 g. AUST R 18655

POISONS SCHEDULE

Nil

FURTHER INFORMATION

Each 7 grams of Normacol Plus (equivalent to one heaped medicinal 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.

STORAGE

Store below 25°C.

SPONSOR

Norgine Pty Ltd

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Frenchs Forest, NSW 2086

Date of TGA Approval – January 2011

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