Normacol Plus

Summary of Product Characteristics Updated 06-Apr-2016 | Norgine Limited

1. Name of the medicinal product
NORMACOL Plus

2. Qualitative and quantitative composition
The active ingredients are 62% Sterculia and 8.0% Frangula Bark

3. Pharmaceutical form
Light brown to dark brown coated granules.

4. Clinical particulars

4.1 Therapeutic indications
The treatment of constipation, 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

Posology
Adults (including older people): 1 or 2 sachets or 1-2 heaped 5ml spoonfuls, once or twice daily after meals.

Paediatric population
Children (6 – 12 years): A reduced amount may be given at the discretion of the physician.

NORMACOL® is not recommended for children under 6 years of age.

Method of administration
The granules should be placed 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 on and taken with soft food such as yoghurt.

4.3 Contraindications
Intestinal obstruction, faecal impaction and total atony of the colon.

Pregnancy and lactation (see section 4.6)

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

4.4 Special warnings and precautions for use

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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.

Patients should be advised to avoid Normacol Plus immediately before going to bed or in a recumbent position (especially if they are elderly) and to suspend treatment if bowel movements do not occur within four days.

Take with plenty of water to reduce the risk of oesophageal obstruction. Adequate fluid intake should be maintained.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of sterculia and frangula in pregnant women. Frangula can cross the placenta and non-clinical studies have shown a potential genotoxic risk (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, although it is reported that excretion of active metabolites from other anthranoids occurs in
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

None known.

4.8 Undesirable effects

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Drug Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune system disorder</td>
<td>Allergic reactions</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Oesophageal obstruction, intestinal obstruction or impaction, abdominal distension, flatulence, diarrhoea, nausea, abdominal pain, melanosis coli</td>
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</tbody>
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**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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

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.

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

Non-clinical safety data for frangula are not available. Although no teratogenic effects have been reported, non-clinical data suggest a possible genotoxic risk for several anthranoids related to frangula. There is also evidence to suggest that products of this class may cross the placenta and small amounts of metabolites may be excreted in milk.

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

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Talc
Sodium hydrogen carbonate
Hard paraffin
Peppermint flavouring
Colourings: E110, E127 and E132

The sugar provides 7 – 14 calories per dose (1.7 to 3.4g carbohydrate per dose). The sodium content is 1.25 to 2.5 mmol per does. NORMACOL Plus is gluten free.

6.2 Incompatibilities

None known.
6.3 Shelf life
Sachet and lined carton: 2 years.

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

6.5 Nature and contents of container
Sachets containing 7g of granules in cartons of 2, 7, 10, 30 or 60 sachets.
Lined carton of 200g or 500g of granules.

6.6 Special precautions for disposal and other handling
None.

7. Marketing authorisation holder
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8. Marketing authorisation number(s)
PL 00322/5011R

9. Date of first authorisation/renewal of the authorisation
01 May 1986/ 01 May 1991

10. Date of revision of the text
March 2016

Legal category
GSL

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