



## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **NORMACOL Plus Granules 62% w/w Sterculia and 8% w/w Frangula Bark**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).
- You must talk to a doctor if you do not feel better or if you feel worse after 4 days.

#### **What is in this leaflet:**

1. What Normacol Plus is and what it is used for
2. What you need to know before you take Normacol Plus
3. How to take Normacol Plus
4. Possible side effects
5. How to store Normacol Plus
6. Contents of the pack and other information

#### **1. What Normacol Plus is and what it is used for**

Normacol Plus granules contain 62% w/w sterculia and 8% w/w frangula bark. Sterculia is a vegetable gum from the karaya tree and frangula bark comes from the alder buckthorn plant. It is these natural products in Normacol Plus which help to relieve constipation and help keep you regular.

Normacol Plus is also used by people who have recently had rectal surgery or surgery to remove piles.

#### **2. What you need to know before Normacol Plus**

**Do not take Normacol Plus if you know or your doctor has told you that you:**

- Have a blockage in your intestine (gut).
- Have total loss of muscle tone in the colon.
- Have faecal impaction.



- Have allergy to the active substance or any of the other ingredients of this medicine (listed in section 6).
- Are pregnant or breast-feeding.

**Talk to your doctor before taking Normacol Plus if:**

- You have ulcerative colitis (an inflammatory disease of the bowel which can cause abdominal pain and bloody diarrhoea)

As with all laxatives, Normacol Plus should not be taken every day for long periods. If you need laxatives every day, you should see your doctor.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Normacol Plus may cause diarrhoea which may result in loss of fluids and a loss in certain salts in your body.

Plenty of water should be taken and maintained in order to reduce the chance of developing oesophageal obstruction (a blockage in the food pipe/gullet).

**Children and adolescents**

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

**Other medicines and Normacol Plus:**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**Normacol Plus with food and drink**

NORMACOL Plus should be taken after meals, always drink plenty of water or soft drinks.

**Pregnancy, breast-feeding and fertility**

Do not take Normacol Plus if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Normacol Plus should not affect your ability to drive or use machines.

**Important information about some of the ingredients of Normacol Plus**

This medicine contains 1.25-2.5 mmol sodium per dose. This should be taken into consideration by patients on a controlled sodium (low salt) diet.



### 3. How to take Normacol Plus

Always take Normacol Plus exactly as described in this leaflet or as your doctor or pharmacist has told you.. You should check with your doctor or pharmacist if you are not sure.

- The usual dose for adults and the elderly is 1 to 2 sachets, or 1 to 2 heaped 5ml spoonfuls, taken once or twice a day after meals. **Do not** take Normacol Plus if you are lying down or just before you go to bed.
- Normacol Plus can be used in children aged between 6 to 12 years but only as directed by a doctor.

If Normacol Plus **does not** work after you have taken it for 4 days, **do not** take anymore, and see your doctor or pharmacist.

- **To take Normacol Plus**, put the dry granules on your tongue from the sachet, spoon or your hand, or just take a few at a time if that is easier.
- Alternatively you can sprinkle Normacol Plus onto soft food such as yoghurt.
- Swallow the granules with plenty of water or a cool drink, so that the oesophagus (gullet) does not become blocked. **Never** chew or crush the granules.

**If you take more Normacol Plus than you should** and do not have bowel movements, see your doctor.

**If you forget to take Normacol Plus**, just take the next normal dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, Normacol Plus can cause side effects, although not everybody gets them:

- The bowel may become blocked and some people may experience stomach pain .
- Occasionally Normacol Plus causes a swollen stomach.
- Flatulence
- The oesophagus (gullet) can become blocked if Normacol Plus is not taken with enough fluid, or too much Normacol Plus is taken.
- Some people may have an allergic reaction which may include an itchy skin, rash, or difficulty in breathing.
- Diarrhoea, which may cause a reduction in the level of salts in the blood.
- Normacol Plus may cause you to feel sick,
- Normacol Plus can result in a discoloration of the colon lining (a condition called melanosis coli.)



If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can provide more information on the safety of this medicine.

## **5. How to store Normacol Plus**

Keep this medicine out of the sight and reach of children.

Store in a dry place below 25°C.

**Do not** use Normacol Plus after the expiry date which is stated on the sachet/carton as month/year. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and ourther information**

### **What Normacol Plus contains**

The active substances are sterculia and frangula bark. The granules contain 62% w/w sterculia and 8% w/w frangula bark.

The other ingredients are sodium hydrogen carbonate, sucrose, talc, hard paraffin, peppermint flavour and the colours E110, E127 and E132.

### **What Normacol Plus looks like and contents of the pack**

Each carton contains 200 or 500 grams of light brown to dark brown granules, or if it is a sachet pack, 60 sachets each containing 7 grams of granules.

### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is Norgine Ltd, Moorhall Road, Harefield, Middlesex, UB9 6NS, UK.

It is made by Norgine Pharma:

29, rue Ethe Virton – 28100 Dreux - France

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