



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

### **NORMACOL Granules 62% w/w Sterculia**

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

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

Normacol granules contain 62% w/w sterculia, which is a vegetable gum from the karaya tree. It is this natural dietary fibre which helps to relieve constipation and help keep you regular.

It is also used by people:

- with colostomies or ileostomies,
- who need a high fibre diet, for example in diverticular disease of the colon,
- who have had rectal or anal surgery,

who have swallowed something sharp to reduce the chance of damage to the intestine (gut).

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

**Do not take Normacol if your doctor has told you that you have:**

- A blockage in your intestine (gut)
- Total loss of muscle tone in the colon
- Faecal impaction
- Allergy to the active substance or any of the other ingredients of this medicine (listed in section 6)



**Talk to your doctor or pharmacist before taking Normacol** if you have ulcerative colitis (an inflammatory disease of the bowel which can cause abdominal pain and bloody diarrhoea).

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 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 foodpipe/gullet ).

**Children and adolescents** Normacol is not recommended in children under 6 years of age.

#### **Other medicines and Normacol**

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 with food and drink**

Normacol should be taken after meals and always drink plenty of water or soft drinks.

#### **Pregnancy, breast-feeding and fertility**

Normacol can be taken if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines**

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

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

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

### **3. How to take Normacol**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. 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 if you are lying down or just before you go to bed.

#### **Use in children**

- The usual dose for children aged 6 to 12 years old is half the adult dose (half to 1 sachet or half to 1 heaped 5ml spoonful).

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

- **To take Normacol**, 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 on to 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 than you should** and do not have bowel movements, see your doctor.

You may develop severe diarrhoea and could become dehydrated. If this happens to you, see your doctor or pharmacist because it may reduce the levels of salts in your body.

**If you forget to take N**, 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 can cause side effects, although not everybody gets them:

- Occasionally Normacol causes a swollen stomach.
- Some people may suffer from wind.
- The bowel may become blocked.
- The oesophagus (gullet) can become blocked if Normais not taken with enough fluid, or too much Normacol is taken.
- Some people may have an allergic reaction which may include an itchy skin, rash or difficulty in breathing.
- It is not unusual for stool to appear paler in colour than normal as a result of local contact with sterculia. This does not indicate anything untoward.
- Some people may experience diarrhoea and stomach pains.
- Some people may feel sick.

Reporting of side effects



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 the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

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

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

Store in a dry place below 25°C.

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

### **What Normacol contains**

The active substance is sterculia. The granules contain 62% w/w sterculia.

The other ingredients are sodium hydrogen carbonate, sucrose, talc, titanium dioxide, hard paraffin and vanillin.

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

Each carton contains 500 grams of white granules, or if it is a sachet pack, 60 sachets each containing 7 grams of white 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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