



PACKAGE LEAFLET: INFORMATION FOR THE USER

NORMACOL® 62% w/w Granules Sterculia

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This medicine is available without prescription but you still need to take NORMACOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get 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.

In this leaflet

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1. What NORMACOL is and what it is used for

NORMACOL granules contain 62% w/w sterculia.

Sterculia is a vegetable gum from the karaya tree. It is this natural dietary fibre in NORMACOL 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)
- your doctor has told you that you have total loss of muscle tone in the colon
- your doctor has told you that you have faecal impaction
- you are allergic (hypersensitive) to the active substances or any of the other ingredients of NORMACOL (listed in section 6).
- your doctor has told you that you have an intolerance to some sugars

Warning and Precautions

Talk to your doctor before taking NORMACOL if:

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

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).



Do not take NORMACOL just before you go to bed or when you are lying down.

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. Always drink plenty of water or soft drinks while you are taking this medicine.

Pregnancy, breast-feeding and fertility

NORMACOL can be taken if you are pregnant or breastfeeding. 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 medicinal product contains 28.7 mg sodium (main component of cooking /table salt) per 7g sachet or 16.8mg of sodium per 5ml spoonful. This is equivalent to 1.5% or 0.9 % of the recommended maximum daily dietary intake of sodium for an adult.

This should be taken into consideration by patients on a controlled sodium (low salt) diet.

This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NORMACOL.

3. How to take NORMACOL

Always take NORMACOL exactly as described in this leaflet or as your doctor or pharmacist have 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 just before you go to bed or when you are lying down.

Use in children

- NORMACOL can be used in children aged between 6 to 12 years but only as directed by a doctor.

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 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 than you should and do not have bowel movements, see your doctor.

You may develop severe diarrhoea and could become dehydrated. This may reduce the levels/balance of salts in your body.



If you forget to take NORMACOL, 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.

Tell your doctor immediately and stop taking NORMACOL if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

You may also experience:

- swollen stomach
- wind (flatulence)
- blocked intestine (gut)
- blocked oesophagus (gullet)
- diarrhoea
- nausea
- abdominal pain

If you take too much NORMACOL:

- The oesophagus (gullet) can become blocked. This can also happen if NORMACOL is not taken with enough fluid.

It is not unusual for stools to appear paler in colour than normal as a result of local contact with the active ingredient NORMACOL (Sterculia). This does not indicate anything untoward.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: www.hpra.ie.

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.

Do not store above 25°C. Store in the original package in a dry place. Keep the carton tightly closed.

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 the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What NORMACOL contains

The active substance is sterculia. Each gram of NORMACOL Granules contains 0.62g of sterculia (62% w/w). The other ingredients are sucrose, talc, sodium hydrogen carbonate, hard paraffin, E171 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, 7 or 60 sachets each containing 7 grams of granules. The granules are white irregular shapes.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Norgine B.V.
Antonio Vivaldistraat 150,
1083 HP Amsterdam,
Netherlands

Manufacturer

Norgine Pharma,
29, rue Ethé Virton,
28100 Dreux,
France

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Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, please ring 00 44 1895 826 606.