



NORMACOL® PLUS GRANULES

62% w/w Sterculia and 8% w/w Frangula

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or 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. Sterculia is a vegetable gum from the karaya tree and frangula 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 and those with diverticulosis (small, bulging sacs or pouches of the inner lining of the intestine).

2. What you need to know before you take Normacol Plus

Do not take Normacol Plus 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 pregnant or thinking about becoming pregnant
- you are breast-feeding
- you are allergic (hypersensitive) to the active substances or any of the other ingredients of Normacol Plus (see section 6).
- you are under 12 years of age

Warning and Precautions

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).

Laxatives containing frangula bark should not be taken by patients suffering from faecal impaction and other stomach complaints such as abdominal pain, nausea and vomiting unless advised by your doctor.

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.

Plenty of water should be taken and maintained in order to reduce the chance of developing oesophageal obstruction (a blockage in the foodpipe/gullet)
Normacol Plus may cause diarrhoea which may result in loss of fluids and a loss in certain salts in your body.

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

Children and adolescents

Normacol Plus is not recommended for use in children under 12 years of age.

Other medicines and Normacol Plus

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

Hypokalaemia or low potassium (resulting from long-term laxative abuse) may effect the action of certain heart medicines such as cardiac glycosides and interacts with antiarrhythmic medicinal products, or other medicines that induce reversion to sinus rhythm (e.g. quinidine) or with medicines inducing QT-prolongation. Concomitant use with other medicines inducing hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

Normacol Plus with food and drink

Normacol Plus should be taken after meals. Always drink plenty of water or soft drinks while you are taking this medicine.

Pregnancy, breast-feeding and fertility

Do not take Normacol Plus if you are pregnant, thinking about becoming pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking any 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. This medicinal product contains 28.7 mg of sodium per 7 g sachet, equivalent to 1.5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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 Plus.

The colour E110 may cause allergic reactions.

3. How to take Normacol Plus

Always take Normacol Plus 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.

Adults (including the elderly) and children aged 12 years and over:

Sachets

One sachet (equivalent to 7g of Normacol Plus) or two sachets (equivalent to 14g of Normacol Plus) per day, after meals.

Or

Granules

One heaped 5ml spoonful (equivalent to 3.5g of Normacol Plus) or two heaped 5ml spoonfuls (equivalent to 7g of Normacol Plus) to be taken once or twice a day, after meals.

The recommended dose of this herbal preparation is equivalent to 10 – 30 mg hydroxyanthracene derivatives, calculated as glucofrangulin A.

Use in children

Normacol Plus is not recommended for use in children under 12 years of age.

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. Swallow immediately with plenty of water or a cool drink.

- Alternatively you can sprinkle Normacol Plus onto soft food such as yoghurt and then immediately drink plenty of water or a cool drink. .

- 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 following side effects have been seen but it is not known how often they occur because the frequency cannot be estimated from the available data:

Tell your doctor immediately and stop taking Normacol Plus 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
 - stomach pain
 - blocked intestine (gut)
 - wind
 - diarrhoea
 - nausea
 - a discoloration in the lining of the colon (melanosis coli)
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- You may become dependent on Normacol Plus and lose your normal bowel function if you take too much or use it for too long.

If you take too much Normacol Plus:

- The oesophagus (gullet) can become blocked. This can also happen if Normacol Plus is not taken with enough fluid
- You may experience extreme diarrhoea which may mean you become dehydrated.

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 Plus

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

Do not store above 25°C. Store in the original package.

Keep the carton tightly closed, in order to protect from moisture.

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.

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 Plus contains

The active substances are sterculia and frangula. Each gram of Normacol Plus granules contains 0.62g (62% w/w) of sterculia and 0.08g (8% w/w) of frangula.

The other ingredients are sodium hydrogen carbonate, sucrose, talc, hard paraffin, peppermint flavour, the colours Sunset yellow FCF (E110), Erythrosine (E127) and Indigo carmine (E132) and sodium chloride.

What Normacol Plus looks like and contents of the pack

Each carton contains 200 or 500 grams of brown granules, or if it is a sachet pack, 7 or 60 sachets each containing 7 grams of granules. The granules are brown irregular shaped with a slight smell and taste of peppermint.

Marketing Authorisation Holder

The Marketing Authorisation Holder is
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This leaflet was last approved in 11/2021

NORMACOL is a registered trademark.

Other Information

If you need the information on this leaflet in an alternative format, such as large text please ring Medical Information from Ireland: 00 44 1895 826 606