

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

NORMACOL 6,2 g per 10 g granules

Sterculia

Contains sugar: Sucrose 2,4593 g

Read all of this leaflet carefully because it contains important information for you

NORMACOL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NORMACOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NORMACOL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve 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 contains the active substance sterculia. Sterculia is a vegetable gum from the Karaya tree. It is a natural dietary fibre.

NORMACOL is a laxative.

- It helps you have a comfortable bowel movement when you are constipated, including constipation during pregnancy and lactation.
- It helps relieve symptoms in patients with irritable bowel syndrome.
- It is also used by people who need a high fibre diet, for example in diverticular disease of the colon, by people with colostomies or ileostomies, by people who have had rectal or anal surgery and by people 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 you are hypersensitive (allergic) to sterculia or any of the other ingredients of NORMACOL (listed in section 6).
- if your doctor has told you that you have a blockage of your intestine (gut), total loss of muscle tone in the colon or faecal impaction.
- if your child is under the age of 6 years.

Warnings and precautions

Take special care with NORMACOL:

- if you have ulcerative colitis (an inflammatory disease of the bowel which can cause abdominal pain and bloody diarrhoea), talk to your doctor before you use NORMACOL.
- if you have stomach pain, nausea or vomiting.
- NORMACOL should not be used for longer than one week, unless directed by a doctor.
- if you have noticed a sudden change in bowel habits that continues for longer than two weeks talk to your doctor before using laxatives.
- if you have rectal bleeding or do not have a bowel movement after use of NORMACOL, stop using NORMACOL and consult a doctor as these may indicate a serious condition.
- NORMACOL should not be taken for more than 4 days if there has been no movement of the bowels.
- if you use laxatives often and for long periods you may become dependent on laxatives and experience loss of normal bowel function.
- if you do not drink enough fluid with NORMACOL, blockage of your intestines can occur.
- plenty of water should be taken and maintained in order to reduce the chance of developing a blockage in the food pipe/gullet.
- do not take NORMACOL immediately before you go to bed or if you are lying down.
- NORMACOL may cause diarrhoea which may result in loss of water and a loss of electrolytes.
- it is not unusual for stool to appear paler in colour than normal. This does not indicate anything untoward.

Other medicines and NORMACOL

Always tell your healthcare provider if you are taking any other medicine (this includes

complementary or traditional medicines).

NORMACOL could interfere with the absorption of other medicines.

Pregnancy, breastfeeding and fertility

NORMACOL can be used for constipation in pregnancy and during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or healthcare provider for advice before taking NORMACOL.

Driving and using machines

NORMACOL has no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent NORMACOL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NORMACOL affects them.

NORMACOL contains sucrose and sodium

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

NORMACOL contains 2,4593 g of sucrose per 10 grams (dose). This should be taken into account in patients with diabetes mellitus.

NORMACOL contains approximately 17 mg sodium in each 5 mL spoon of NORMACOL granules that is to say essentially 'sodium-free'. The WHO recommended maximum daily intake of sodium for an adult is 2 grams.

3. How to take NORMACOL

Do not share medicines prescribed for you with any other person.

Always take NORMACOL exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adolescents and adults (including the elderly):

Take one to two heaped medicine measures, once or twice daily.

Take after meals.

NORMACOL generally produces a bowel movement in 12 to 72 hours.

Children (6 to 12 years):

One half the adult dose or as directed by the medical practitioner or pharmacist.

Put the dry granules on your tongue, in small quantities if necessary. Swallow the granules down immediately with plenty of water or a cool drink. Never chew or crush the granules.

Always drink plenty of water or soft drinks while you are taking NORMACOL so that the oesophagus (gullet) does not become blocked.

Alternatively, you can sprinkle NORMACOL on to soft food such as yoghurt and then immediately drink plenty of water or a cool drink.

If you take more NORMACOL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take NORMACOL

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NORMACOL can have side effects..

Not all side effects reported for NORMACOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORMACOL, please consult your healthcare provider for advice.

If any of the following happens, stop taking NORMACOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to NORMACOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blockage of your intestines (bowel) or oesophagus (gullet) is possible if NORMACOL is taken in overdose or is not adequately washed down with fluids.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Full feeling in the stomach, flatulence (wind), diarrhoea, feeling sick, stomach pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of NORMACOL.

5. How to store NORMACOL

Store all medicines out of reach of children.

Store in a dry place, at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NORMACOL contains

The active substance per 10 g of NORMACOL granules is 6,2 g sterculia.

The other ingredients are paraffin hard, sodium hydrogen carbonate (for pH adjustment), sucrose, talc, titanium dioxide, vanillin.

Contains sugar: Sucrose 2,4593 g

NORMACOL is gluten free.

What NORMACOL looks like and contents of the pack

White irregular shaped granules.

500 g is packed in a laminated, Kraft paper and low density polyethylene liner bag which is glued into an outer cardboard carton.

HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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This leaflet was last revised in

10 June 2022

Registration number

E1974 (Act 101 of 1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088



Botswana: BOT0801456 S4

Namibia: NS0 05/11.5/0441

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