

## Package leaflet: information for the user

### NORMACOL Granules

#### Sterculia urens Roxb., gum

Read carefully the entire leaflet before you take this goes use because there states important information in for you.

Use this medicine always exactly as in this leaflet described or such as your doctor or pharmacist you has told you.

- Keep this leaflet. You may need it later again ..
- need you still questions? Then contact your pharmacist.
- Do you experience one of the side effects listed in section 4 mentioned? Or do you a side effect that not in this leaflet is listed? Then contact your doctor or pharmacist.
- Does your complaint after 4 days not less, or becomes he even worse? Contact your doctor.

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#### 1. What is Normacol and what is it usedfor

? Normacol a laxative (bulk-forming agent). It is indicated for the treatment of the symptoms of constipation, except constipation of mechanical origin. Normacol is indicated for use in adults, adolescents and children from 6 years.

Does your complaint after 4 days not less, or becomes he even worse? Then contact your doctor.

#### 2. When should you Normacol not use or must you be extra careful with are?

##### When may you Normacol not use?

- You are allergic to one of the ingredients in this medicine. These substances can you find in section 6 of this leaflet
- in narrowing and/or obstruction of the digestive system
- in very severe constipation, fecal impaction called
- in lack of muscle tone of the large intestine (colonic atony)
- in abdominal pain without clear cause
- in nausea and vomiting.

##### When should you be extra careful with Normacol ?if

- you use it long-term . In case ofchronic constipation will will men first attempt this condition to remedy by adjustment of the dietary- and lifestyle habits.
- if you take it when you of you of plan bent on to go lie (rest/sleep). Normacol should not be taken just before going to sleep sleep go or in a lying position.

- if you have difficulties with swallowing . The intake should be avoided when having to be in patients who difficulties have with swallowing ..
- you have diarrhea . In case of severe diarrhea there is a chance on a fluid- and electrolyte deficiency. In this case you should drink enough to drink.
- if you can drink little. Take Normacol with a large amount of water or other liquid. This serves to prevent at the level of the digestive system to prevent. Sufficient fluid intake must be ensured guaranteed.
- your doctor has informed you that you cannot tolerate certain sugars , contact your doctor before you this medicine take. See also section "Normacol contains sucrose and sodium".
- it is possible that the stool lighter of color is when you Normacol use. You do not need to worry further about it to worry.

Contact your doctor or pharmacist before you take this medicine ..

Normacol

is not recommended for children under the the age from 6 years.

Do you any other medications?

Do you besides Normacol any other medications, do you that short ago done or going you this perhaps soon do? Tell that then your doctor or pharmacist.

Whereupon must you pay attention with food and drink

Not applicable applicable.

Pregnancy, breastfeeding and fertility

Are you pregnant, think you pregnant to be, do you want to become pregnant or are you breastfeeding? Then contact your doctor or pharmacist before you use this medicine.

Normacol may be used after advice from a doctor during pregnancy . Normacol.

be used during the breastfeeding period during the breastfeeding period.

There are no data on the effect of Normacol on fertility in humans available.

Driving ability and the use of machines

Normacol has no influence on the driving ability and on the ability to operate machines to operate.

Normacol contains sucrose and sodium

If your doctor has told you informed that you certain sugars do not tolerate, contact your doctor before you this medicine take.

Contains 2.5 g sucrose per dose for adults (amount in 1 sachet of 10 g). Caution is advised in patients with diabetes mellitus.

This medication contains 41 mg sodium (an important component of table salt) per dose for adults (amount in 1 sachet of 10 g). This corresponds to 2% of the recommended maximum daily amount sodium in the nutrition for an adult.

3. How do you take Normacol

? Use this medicine always exactly as in this state or as your doctor or pharmacist you that has told. Are you unsure about the correct use? Then contact your doctor or pharmacist. If there is no improvement occurs after 4 days, consult your doctor again ..

#### Normacol Oral

use : place the: lay the granules dry on the tongue and swallow them without chewing or crushing immediately by with a large amount water or a cool drink. You can they also on soft food such as yogurt sprinkle and so take. Drink then immediately a lot of water or a different cool drink. In case of children can one the recommended dose mix with jam or let swell in a little water or other liquid. Drink immediately after intake another one large glass water or a other liquid.

Adolescents and adults:

1 to 2 teaspoons or 1 sachet, 2 to 3 times per day after the meals

Use in children from 6 to 12 years:

½ to 1 teaspoon or ½ sachet, 2 to 3 times per day after the meals

The active effect of *Sterculia urens* Roxb., gum is observed between 1 and 3 days after intake, as is the case with in all fibers.

Have you too much of Normacol taken?

If you too much of Normacol have taken, then contact immediately contact your doctor, pharmacist or the Poison Control Center (070/245.245).

The preparation can, taken dry ,cause a blockage of the intestines cause. Therefore should one in case of overdose a lot of water to drink. If you severe diarrhea have, there is the risk of dehydration a a electrolyte deficiency. You should then sufficiently to drink.

Did you forget Normacol in to take?

Do not take double dose to a missed dose in to catch up, but just take your next dose at the time as this was scheduled ..

Has you still other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine can also this medicine side effects have. Not everyone experiences them . Immune system disorders.

Allergic:

- Gastrointestinal disorders :

Gastrointestinal disorders:

- Distension of the lower abdomen
- Obstruction of the esophagus
- Diarrhea
- Nausea
- Abdominal pain

- Sometimes occurs flatulence , which disappears with adjustment of the dose.
- Cases of constipation or impaction (constipation due to hardened stool) at the level of the intestine have also been described. This occurs generally general for in insufficient fluid intake in elderly patients or in the presence of a narrowing at the level of the digestive system.

#### The report of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also to side effects that are not in this leaflet stand. U can side effects also report via:

Federal agency for medicines and health products  
Department Vigilance

Galileelaan, 5/03  
1210 BRUSSELS

P.O. Box 97  
B-1000 BRUSSELS Madou

Website: [www.eenbijwerkingmelden.be](http://www.eenbijwerkingmelden.be)  
e-mail: [adr@fagg.be](mailto:adr@fagg.be)

By reporting side effects to report, you help us to obtain more information about the safety of this this medicinal product.

#### 5. How to store you Normacol?

Keep out of sight and reach of children ..

with 1 sachet of 375 g: of 375 g:

Store below 25 °C and in the original packaging.

The box carefully closed keep to protect against moisture.

Shelf life after opening: 3 months.

Box with 30 sachets of 10 g:

Store below 25 °C.

Store in the original packaging to protect against moisture.

Use this medicine not more after the expiry date. You find it on the box and the sachets after "EXP". There is a month a a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or the toilet and a throw them not in the trash can. Ask your pharmacist what to do with medicines you should do that you no longer use . If you medicines correct way disposes be they in a correct way destroyed and enter they not into the environment end up.

#### 6. Contents of the package en other information

Which substances are in Normacol?

- The active ingredient in Normacol is: Sterculia urens Roxb., gum. (62 g per 100 g granulate)

- The other ingredients in Normacol are: Sodium bicarbonate, talc, titanium dioxide (E171), paraffin (solid), vanillin, sucrose (see section 2 "Normacol contains sucrose en sodium").

How does Normacol look and what is in a package?

Normacol Granules are small white, irregularly shaped grains to in to take via the mouth.

Normacol is available in a box with 1 sachet of 375 g granules (sachet consisting of paper/low density polyethylene). Normacol is also available in a box with 30 sachets of 10 g (sachets consisting of paper/low density polyethylene/aluminum/low density polyethylene).

Holder of the authorization for placing on the market ::

N.V. ,, Haasrode Research Park, Romeinsestraat 10, B-3001 Heverlee

Manufacturer:

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

Numbers of the license for placing on the market ::

Normacol in a box with 1 sachet of 375 g: BE016484

Normacol in a box with 30 sachets of 10 g: BE498604

Method of delivery: Free delivery

This leaflet is for the last approved in 01/2021.