

Package leaflet: Information for the user

NORGALAX rectal gel

docusate sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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.

What is in this leaflet

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

1. What Norgalax is and what it is used for

Norgalax softens the faeces (stools) to make your bowel movements easier. It will help you when you are constipated or can be used to empty the large intestine (gut) if the doctor wants to examine inside it.

2. What you need to know before you use Norgalax

Do not use Norgalax

- if you are allergic to docusate sodium or any of the other ingredients of this medicine (listed in section 6).
- if you have haemorrhoids (piles) or bleeding from your rectum (back passage).
- if you have a pain in your abdomen (tummy).
- if you feel sick or are being sick.
- if you have a blockage in your intestine (gut).
- if you have sores around your anus (bottom) called anal fissures.
- if you have inflammatory bowel disease such as ulcerative colitis or Crohn's disease.
- if you have inflammation of the back passage called rectocolitis.
- if you have a bowel condition called "ileus" (loss of muscle tone in the bowel).

Warnings and precautions

Talk to your doctor or pharmacist before using Norgalax.

Prolonged use can cause the gut to become lazy and not work properly. It can also lead to low levels of potassium in the blood (called 'hypokalaemia').

Children

Norgalax should not be used in children under 12 years old.

Other medicines and Norgalax

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

The liver may be affected (signs include yellowing of the skin and eyes, bruising or itching) especially if other laxatives are being used as well as Norgalax.

Pregnancy and breast-feeding

Do not use Norgalax if you are pregnant or breast-feeding unless your doctor has told you to do so.

Norgalax contains glycerol

Norgalax contains glycerol (E 422). May have a mild laxative effect.

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3. How to use Norgalax

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 12 years and over

The recommended dose is one tube and this is usually all you need. You can use a second tube later in the day, or the next day if needed.

Do not use Norgalax for more than a few days at a time.

To use Norgalax:

- Pull the cap off the neck of the tube.
- Gently squeeze the tube and smear a drop around the neck of the tube to help it slide in.
- Push the neck of the tube all the way into your rectum (back passage). Squeeze the tube gently until it is empty.
- Stay near a toilet because you should need to use it about 5 to 20 minutes after using Norgalax.

If you use more Norgalax than you should, contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Sometimes there is burning or pain around the anus (bottom). The wall of the rectum (back passage) may become reddish or it may bleed and you may suffer from diarrhoea but this soon goes.

Some people may also experience an itchy skin rash.

The liver may be affected (signs include yellowing of the skin and eyes, bruising or itching) especially if other laxatives are being used as well as Norgalax.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Norgalax

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

Do not use this medicine after the expiry date which is stated on the carton after 'Exp' and the end of the tube as month/year. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away 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 Norgalax contains

- The active substance is docusate sodium. Each tube contains 0.12 g docusate sodium.
- The other ingredients are glycerol (E 422), carmellose sodium and purified water. See section 2 "Norgalax contains glycerol".

What Norgalax looks like and contents of the pack

Norgalax is a rectal gel. Norgalax is available in a tube with fixed applicator and a cap closure, containing 10 g of gel. Each pack contains either 6 or 100 tubes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Pharma Ltd., Crabtree Road, Egham, Surrey, TW20 8RB UK.

Manufacturer

Purma Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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