

Package leaflet: Information for the user

Laxogol Powder for oral solution, sachet

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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 after 14 days.

What is in this leaflet:

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

1. What Laxogol is and what it is used for

Laxogol is a laxative used for the treatment of long time constipation. It is not recommended for children below 12 years of age. Macrogol 3350 makes your faeces softer and easier to pass, giving you relief from constipation. The electrolytes (salts) help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

2. What you need to know before you take Laxogol

Do not take Laxogol

- if you are allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients of this medicine (listed in section 6)
- if you have a perforated gut (bowel) wall
- if you have a blockage in your intestine (gut obstruction, ileus)
- if you have severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon

If any of these applies to you, please talk to your doctor or pharmacist for further advice.

Other medicines and Laxogol

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Laxogol. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Laxogol with food and drink

Laxogol can be taken at any time with or without food or drink

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your

doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Laxogol has no effect on the ability to drive or use machinery.

Laxogol contains potassium, sodium and sorbitol (lemon lime flavour)

Laxogol contains 0.63 mmol (25 mg) of potassium per sachet. This should be taken into consideration if you take more than one sachet daily and you have reduced kidney function, or if you are on a controlled potassium diet.

Laxogol contains 8.1 mmol (187 mg) of sodium per sachet. This should be taken into consideration if you are on a controlled sodium diet.

The lemon lime flavour in Laxogol contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Laxogol

Adults, children (aged 12 years and above) and the elderly:

The usual dose for constipation is one sachet taken one to three times daily.

How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or a quarter pint of water to the glass. Stir well until the powder has dissolved and then drink it.

Duration of treatment

This course of treatment for constipation should not normally last longer than 2 weeks.

If you take more Laxogol than you should

This can cause severe pain and swelling in your abdomen (stomach), or vomiting (sickness) or diarrhoea. If this happens, contact your doctor or pharmacist.

If you forget to take Laxogol

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Laxogol

To get the most benefit from Laxogol, always finish the course of treatment according to the directions in this package leaflet. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist.

You must contact a doctor if your symptoms worsen or do not improve after 14 days.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking Laxogol and see your doctor immediately:

- signs of an allergy, such as a rash, itching, shortness of breath or difficulty in breathing.

- signs of a change in your body's fluid or electrolyte levels (salts levels), such as swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache

The following side effects are also possible:

- abdominal (stomach) pain
- mild diarrhoea (when starting to take Laxogol, this usually stops if you reduce the number of sachets you take)
- nausea (feeling sick)
- vomiting
- swelling of your abdomen (feeling bloated)
- stomach rumbling
- flatulence (wind)
- soreness of the anus (bottom)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Laxogol

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 and sachet. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not use this medicine if you notice that any of the sachets is damaged.

Reconstituted Laxogol solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

Do not throw away any 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 Laxogol contains

The active substances are:

Each sachet contains:

macrogol 3350 (polyethylene glycol 3350)	13.125 g
sodium chloride	0.3507 g
sodium hydrogen carbonate	0.1785 g
potassium chloride	0.0466 g

The other ingredients are colloidal anhydrous silica, saccharin sodium, orange flavour (Orange flavour contains: flavouring substances and flavouring preparations, maltodextrin, acacia gum, alpha-tocopherol) and lemon lime flavour (Lemon lime flavour contains: flavouring preparations, maltodextrin, mannitol, gluconolactone, sorbitol (E420), acacia gum, colloidal anhydrous silica).

What Laxogol looks like and contents of the pack

Laxogol is a white powder.

Each sachet contains 13.8 g of powder and is packed in cartons containing 2, 6, 8, 10, 20, 30, 50, 60 (2x30) and 100 (2x50) sachets.

Not all of these pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

Klocke Pharma-Service GmbH
Strassburger Strasse 77
77767 Appenweier
Germany

Hermes Pharma Ges.m.b.H.
Allgäu 36
9400 Wolfsberg
Austria

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