

Package leaflet: Information for the user

Laxatev 13.8 g Powder for Oral Solution

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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1. What Laxatev is and what it is used for

The name of this medicine is *Laxatev 13.8 g powder for Oral Solution*. It is a laxative for the treatment of chronic constipation and of very bad constipation (called faecal impaction) in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

It helps you to have a comfortable bowel movement even if you have been constipated for a long time.

2. What you need to know before you take Laxatev

Do not take *Laxatev*

- 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.

Warnings and precautions

When taking *Laxatev* you should continue to take plenty of fluids. The fluid content of *Laxatev* should not replace your regular liquid intake.

Other medicines and *Laxatev*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics (medicines for epilepsy), may not work as effectively during use with *Laxatev*.

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.

Laxatev can be taken during pregnancy and whilst breast-feeding.

Driving and using machines

Laxatev does not affect your ability to drive or use machines.

***Laxatev* contains potassium, sodium and sorbitol**

Laxatev contains 0.63 mmol (25 mg) 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.

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

The lemon lime flavour in *Laxatev* contains sorbitol. 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 *Laxatev*

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

This medicine can be taken at any time with or without food.

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

Chronic constipation (constipation for a long time)

The recommended dose for constipation is one sachet taken one to three times daily according to your individual response.

Faecal impaction (complete severe constipation)

Before you take this medicine for faecal impaction, it should be confirmed that you have this condition.

The recommended dose for faecal impaction (complete severe constipation) is 8 sachets daily. The 8 sachets should be taken within a 6 hour period each day. Treatment may be continued for up to 3 days if required.

Patients with a heart condition:

Do not take more than 2 sachets in one hour.

Use in children (below 12 years of age)

Laxatev is not recommended for children under 12 years old. Alternative products are available for children below 12 years of age.

Method of administration

Open the sachet and pour the contents into a glass. Add about 125 ml of water to the glass. Stir well until all the powder has dissolved and the solution is clear or slightly hazy, then drink it. If you are taking *Laxatev* for faecal impaction it may be easier to dissolve all 8 sachets in 1 litre of water and to drink the solution evenly spread over a 6 hour period. Reconstituted *Laxatev* solution should be covered and stored in the refrigerator (2°C to 8°C).

Duration of treatment

Constipation:

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

On your doctor's advice, you may need to take *Laxatev* longer than two weeks if you have ongoing constipation, or a disease that causes constipation (such as Parkinson's disease or multiple sclerosis), or if you are taking other regular medicines that can cause constipation. In these cases, your doctor may advise you to reduce your dose to one sachet taken one or two times daily.

Faecal impaction:

Treatment with *Laxatev* can be up to 3 days.

If you take more *Laxatev* than you should

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking *Laxatev* and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take *Laxatev*

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 *Laxatev*

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

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.

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

- signs of an allergic reaction, such as shortness of breath or difficulty in breathing, swelling of the face, lips, tongue or throat, nettle rash, itching, skin rash or reddening of the skin,
- signs of a change in your body's fluid or electrolyte levels, such as swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache.

Other side effects include:

- stomach pains
- stomach rumbles
- diarrhoea. You may have mild diarrhoea when starting to take *Laxatev* which generally gets better if you reduce the number of sachets you take
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom)
- swollen stomach
- wind
- swollen hands, feet or ankles
- headaches
- indigestion
- high or low levels of potassium in the blood.

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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Laxatev*

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 use this medicine if you notice that any of the sachets is damaged.

Do not store above 25°C.

If reconstituted *Laxatev* solution cannot be taken straight away, it should 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 *Laxatev* contains

The active substances are:

macrogol 3350	13.125 g
sodium chloride	0.3507 g
sodium hydrogen carbonate	0.1785 g
potassium chloride	0.0466 g

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

What *Laxatev* looks like and contents of the pack

Laxatev is a white powder.

Each sachet contains 13.8 g of powder and is packed in cartons containing 20, 30 and 50 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren
Germany

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

Teva Pharma B.V.
Swensweg 5
2031 Haarlem
The Netherlands

Klocke Pharma-Service GmbH:
Straßburger Straße 77
77767 Appenweier
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom Macilax 13.8 g Powder for Oral Solution

Belgium Curapeg 13,8 g poeder voor drank

Netherlands Macrogol en electrolyten ratiopahrm 13,7 g, poeder voor drank

Ireland Laxatev 13.8 g Powder for Oral Solution

This leaflet was last revised in August 2017.