

Package leaflet: Information for the patient

BENLAXID 13,7 g poeder voor drank
macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Benlaxid is and what it is used for
2. What you need to know before you take Benlaxid
3. How to take Benlaxid
4. Possible side effects
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1. What Benlaxid is and what it is used for

The name of this medicine is Benlaxid Powder for oral solution. It is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

Benlaxid helps you to have a comfortable bowel movement even if you have been constipated for a long time. Benlaxid also works in very bad constipation called faecal impaction

2. What you need to know before you take Benlaxid

Do not take Benlaxid if your doctor has told you that you have:

- an allergy to the active substances or any of the other ingredients of this medicine (listed in section 6).
- a blockage in your intestine (gut obstruction, ileus),
- a perforated gut wall,
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon,

Warnings and precautions

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

Heart conditions

Follow the special instructions in section 3 if you are taking Benlaxid for faecal impaction

Other medicines and Benlaxid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is recommended to wait at least 2 hours between the intake of Benlaxid and other medicinal product

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Benlaxid .

If you need to thicken fluids in order to swallow them safely, Benlaxid may counteract the effect of the thickener.

Pregnancy and breast-feeding

Benlaxid can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before giving Benlaxid .

Driving and using machines

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

Benlaxid contains sodium, and aspartame and potassium

Benlaxid contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need four or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

This medicine contains 5.0 mmol potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains 25 mg aspartame in each sachet .Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly

3. How to take Benlaxid

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

Dissolve the content of each sachet in 125ml of water and drink.

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

Constipation:

A dose of Benlaxid is 1 sachet dissolved in 125 ml (1/4 pint) of water. Take this 1 –3 times a day according to the severity of your constipation.

Faecal impaction:

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

A dose of 8 sachets a day of Benlaxid is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (1/4 pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Benlaxid solution is clear or slightly hazy, then drink it. If you are taking Benlaxid for faecal impaction it may be easier to dissolve 8 sachets in 1 liter of water.

Duration of treatment:

Constipation:

Treatment with Benlaxid usually lasts for about 2 weeks. If you need to take Benlaxid for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take Benlaxid for longer than 2 weeks. If you need to take Benlaxid for longer, please see your doctor.

Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Benlaxid can be for up to 3 days.

If you take more Benlaxid than you should:

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

If you forget to take Benlaxid :

Take the dose as soon as you remember to take it.

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

4. Possible side effects

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

Tell your doctor immediately and stop giving Benlaxid if you:

- gets a serious allergic reaction which causes difficulty in breathing or swelling of the face, lips, tongue or throat.

Very common(may affect more than 1 person in 10 people)

- stomach pains
- stomach rumbles

Common (may affect up to 1 in 10 people)

- diarrhoea
- vomiting (being sick)

- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom).

If you are being treated for **chronic constipation**, diarrhea will usually improve when the dose is reduced

Uncommon (may affect up to 1 in 100 people)

- swollen stomach
- wind

Rare (may affect up to 1 person in 1,000 people)

- allergic reactions, which may include, breathlessness or difficulty in breathing.

Not known (frequency cannot be estimated from the available data)

- skin rash (hives), itching, reddening of the skin or a nettle rash,
- dyspnoea,
- angioedema,
- swollen hands, feet or ankles,
- headaches,
- indigestion,
- high or low levels of potassium in the blood,
- peri-anal inflammation.

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 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 Benlaxid

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 sachet and carton after 'EXP'. The expiry date refers to the last day of that month.

Unopened sachet: No special storage conditions are required for the unopened sachet

A prepared solution should be kept covered in a refrigerator (at 5 ± 3 °C) or at room temperature (19°C-25°C) and should be used within 24 hours.

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

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 Benlaxid contains

Each sachet of <Product name> contains the following:

Macrogol 3350	13,125 g
Sodium chloride	0,3507 g
Sodium hydrogen carbonate	0,1785 g
Potassium chloride.	0,0466 g

The other substances in this agent are: Orange Flavour (maltodextrin (maize), Arabic gum (E414), citric acid (E330), butylated hydroxyanisole (E320) and other flavouring substances), Lemon Flavour (maize maltodextrin, flavouring preparations, flavouring substances ,natural flavouring substances, alpha-tocophero(E307)), , Aspartame (E951) and Sucralose

When it is made into a drink with 125ml (1/4 pint) of water, each sachet gives the equivalent of:

Sodium	65 millimoles/litre
Chloride	53 millimoles/litre
Potassium	5.0millimoles/litre
Bicarbonate	17 millimoles/litre

What Benlaxid looks like and contents of the pack

Powder for oral solution.

Benlaxid is a white crystalline powder. <Product name> is available in a carton of 20 & 30 sachets with powder.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Italfarmaco, S.A.
Calle San Rafael 3
28108 Alcobendas, Madrid
Spanje

Manufacturer

Recipharm Höganäs AB

Sporthallsvägen 6
263 34 Höganäs
Zweden

In het register ingeschreven onder RVG 128631.

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

Netherland:	BENLAXID 13,7 g poeder voor drank
Spain:	BIMOTIL 13,7 g polvo para solución oral
Italy:	BENLAXID 13,7g polvere per soluzione orale

Greece: BIMOTIL 13.7g Κόνις για πόσιμο διάλυμα

Deze bijsluiter is voor het laatst goedgekeurd in januari 2023.