

Package leaflet: Information for the patient

BENLAXID 6,9 g poeder voor drank
macrogol 3350,sodium chloride,sodium hydrogen carbonate,potassium chloride

Read all of this leaflet carefully before you give this medicine to your child 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- ✓ If your child gets 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 give Benlaxid
3. How to give Benlaxid
4. Possible side effects
5. How to store Benlaxid
6. Contents of the pack and other information

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 chronic constipation in children aged 1 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

Benlaxid helps your child to have a comfortable bowel movement even if they have been constipated for a long time.

2. What you need to know before you give Benlaxid

Do not give Benlaxid if your doctor has told you that your child has:

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

If your child has a heart or kidney problem, an impaired gag reflex or reflux oesophagitis (heart-burn caused by back-flow of stomach contents into the oesophagus), you should talk to your doctor before giving Benlaxid .

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.

Other medicines and Benlaxid

Tell your doctor if your child is taking or has 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. When taking large volumes of Benlaxid (e.g. for faecal impaction), your child should not take other medicines within one hour of taking 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 given during pregnancy and whilst 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 93.4 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.6% 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 12.5 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 give Benlaxid

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

Dissolve the content of each sachet in 62.5 ml (1/4 of a glass) of water and drink.

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

Chronic Constipation:

The dose of Benlaxid depends on the age of the child and their response to treatment.

- As a starting dose, children aged 1 to 6 years should be given 1 sachet (=1 dose) each day.
- Children aged 7 to 11 should be given 2 sachets each day.

Your doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement. If the dose does need increasing, this should be done every other day. For children below 2 years of age, no more than 2 sachets should be taken in one day. For children 2 to 11 years, normally, no more than 4 sachets are required to be taken in one day.

It is not necessary to take all of the drink at one time, if the child prefers it, half the drink can be taken in the morning and half in the evening.

Faecal impaction:

Before your child takes Benlaxid for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment with Benlaxid is as follows:

Age (years)	Number of Benlaxid sachets						
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5-11	4	6	8	10	12	12	12

The daily number of sachets should be taken in divided doses, all taken within 12 hours (e.g. 8am – 8pm). Each sachet dissolved in 62.5 ml (1/4 of a glass) of water. Treatment can be stopped when the medicine has worked. This is shown by your child passing large volumes of stool and/or watery diarrhoea.

How to mix

- Open the sachet and pour the contents into a glass. Add about 62.5 ml or 1/4 glass of water to the glass. Stir well until all the powder has dissolved and the Benlaxid solution is clear or slightly hazy, then give it to your child to drink.
- If you like you can add a flavour such as orange squash to the drink. If your child is taking Benlaxid for faecal impaction it may be easier to dissolve 12 sachets in 750ml of water.

Duration of treatment**Chronic constipation:**

Treatment needs to be for a prolonged period of time, at least 6 – 12 months.

Faecal impaction:

Treatment with Benlaxid can be for up to 7 days.

If your child takes more Benlaxid than they should:

Your child may develop excessive diarrhoea. If this occurs, stop taking Benlaxid and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Benlaxid :

Give the dose as soon as you remember.

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 your child:

- 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 your child is being treated for **chronic constipation**, diarrhoea 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 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 6.9g sachet of Benlaxid contains the following:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Hydrogen Carbonate	0.0893 g
Potassium Chloride	0.0233 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-tocopherol (E307)), aspartame (E951) and Sucralose.

When it is made into a drink with 1/4 glass (62.5ml) of water, each sachet gives the equivalent of:

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

What Benlaxid looks like and contents of the pack

Powder for oral solution.

Benlaxid is a white crystalline powder. Benlaxid 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 128690.

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

Netherlands:	BENLAXID 6,9 g poeder voor drank
Spain:	BIMOTIL 6,9 g polvo para solución oral
Italy:	BENLAXID 6,9 g polvere per soluzione orale
Greece:	BIMOTIL 6.9 g Κόνις για πόσιμο διάλυμα

Deze bijsluiter is voor het laatst goedgekeurd in januari 2023.