

Package leaflet: Information for the user

Omnilax 10 g, powder for oral solution in sachet

macrogol 4000

[For medicines available on prescription only:]

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.

[For medicines available without prescription:]

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, pharmacist or nurse 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 after 14 days.

What is in this leaflet

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

Omnilax contains the active substance macrogol 4000 and belongs to a group of medicines called osmotic laxatives. It works by adding water to the stools, which helps to overcome problems caused by very slow bowel movements. Omnilax is not absorbed into the bloodstream or broken down in the body.

Omnilax is used for the treatment of constipation in adults and children aged 8 years and above. This medicine is a powder that you dissolve in a glass of water (at least 50ml) and drink. It usually takes 24 to 48 hours to work.

The treatment of constipation with any medicine should only be in addition to a healthy lifestyle and diet.

[For medicines available without prescription:]

Self-treatment of short term constipation should not be carried out for longer than 14 days. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Omnilax

Do not take Omnilax:

- if you are allergic (hypersensitive) to macrogol (polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6).
- if you have an existing disease, such as, severe intestinal disease:
 - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease, abnormal dilation of the bowel)

- perforation of the bowel or risk of perforation of the bowel
 - ileus or suspicion of intestinal obstruction
- painful abdominal syndromes of uncertain cause

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking the medicine.

Warnings and precautions

Cases of allergic reactions involving rash and swelling of the face or throat (angioedema) have been reported in adults after taking products containing macrogol (polyethylene glycol). Isolated severe allergic reactions have been reported causing faintness, collapse or breathing difficulties and feeling generally unwell. If you experience any of these symptoms you should stop taking Omnilax and seek medical help immediately.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before taking this medicine if you:

- have impaired liver or kidney function,
- are taking diuretics (water tablets) or are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood.

Before taking Omnilax, talk to your doctor or pharmacist if you know that you have a swallowing disorder”.

Avoid mixing Omnilax and starch-based food thickeners if you have difficulties with swallowing. This may result in a watery liquid which could get into your lungs and cause pneumonia if you can't swallow properly.

Other medicines and Omnilax

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with Omnilax, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have swallowing problems and need food thickeners to thicken fluids in order to swallow them safely, avoid mixing Omnilax with starch-based food thickeners. Omnilax may counteract the effect of starch-based food thickeners causing preparations that need to remain thick for people with swallowing problems to liquefy.

Pregnancy and breastfeeding

Omnilax can be used during 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

No studies on the effects on the ability to drive and /or use machines have been performed.

Important information about some of the ingredients of Omnilax

This medicine contains 0.7 mg of sorbitol in each sachet. Omnilax can, however, be used if you are diabetic or on a galactose- free diet.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially “sodium-free”.

3. How to take Omnilax

[For medicines available on prescription only:]

Always take Omnilax exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription:]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 8 years

The recommended dose is 1-2 sachets per day, preferably taken as a single dose in the morning. The daily dose can be adjusted according to the effect obtained and may range from one sachet every other day (especially in children) to up to a maximum of two sachets per day.

Dissolve the contents of the sachets in a glass of water (at least 50 mL) immediately before use and drink the liquid.

Please note:

- Omnilax usually takes 24 to 48 hours to work.
- In children, the duration of treatment with Omnilax should not exceed 3 months.
- Improvement in the frequency of your bowel movements after taking Omnilax can be maintained by keeping to a healthy lifestyle and diet.
- Talk to your pharmacist or doctor if the symptoms worsen or do not improve.

[For medicines available without prescription:]

- It usually takes 24 to 48 hours for Omnilax to work.
- Treatment with Omnilax should not be carried out for longer than 14 days. Talk to your doctor if you don't feel better or if you feel worse after 14 days.
- After treatment with Omnilax, the improvement of the bowel movements can be maintained by keeping to a healthy lifestyle and diet.

If you take more Omnilax than you should

Taking too much Omnilax may cause diarrhoea, stomach pains or vomiting. The diarrhoea usually disappears when treatment is stopped or the dose reduced.

If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts (electrolytes) from fluid loss.

If you forget to take Omnilax

Take the next dose as soon as you remember but do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

The side effects that are usually mild and do not last long include:

In children :

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Diarrhoea which may also cause soreness around the back passage (anus).

Uncommon (may affect up to 1 in 100 people)

- Nausea (feeling sick) or vomiting
- Abdominal (belly) bloating

Not known (frequency cannot be estimated from available data)

- Allergic (hypersensitive) reactions (rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse)

In adults:

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Abdominal (belly) bloating
- Nausea (feeling sick)
- Diarrhoea

Uncommon (may affect up to 1 in 100 people)

- Vomiting
- Urgent need to go to the toilet
- Faecal incontinence

Not known (frequency cannot be estimated from available data)

- Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
 - Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Dehydration caused by severe diarrhoea especially in the elderly
- Symptoms of an allergic reaction such as skin redness, rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse

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 Omnilax

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

Do not take Omnilax after the expiry date which is stated on the base of the carton. The expiry date refers to the last day of that month.

Reconstituted solution should be stored well covered in a refrigerator (2°C-8°C) and is stable for 6 hours.

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 Omnilax contains

- The active substance is macrogol. One sachet contains 10 g macrogol.

The other ingredients are:

- saccharin sodium (E954) and flavour (orange-grapefruit aroma containing maltodextrin, sorbitol (E420), butylhydroxyanisole (E320) and gum arabic (E414)).

What Omnilax looks like and contents of the pack

Off white powder with a taste of orange-grapefruit.

Omnilax is available in pack sizes of [pack sizes to be completed nationally] sachets (not subject to medical prescription) and [pack sizes to be completed nationally] sachets (subject to medical prescription).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pro Health Pharma Sweden AB
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Manufacturer

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