



Package leaflet:
Information for the user

Macrogol 10 g powder for oral solution

Macrogol 4000

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

1. What Macrogol is and what it is used for

Macrogol contains the active substance macrogol 4000 and belongs to a group of medicines called osmotic laxatives. Macrogol carries water to your stool, which loosens and increases stool volume, helping to overcome sluggish bowels. Macrogol is not absorbed into the bloodstream or broken down in the body. Macrogol is used for the treatment of constipation in adults and children aged 8 years and over. Macrogol is a powder that you dissolve in a glass of water (at least 50 ml) and then drink. Macrogol works gradually within 24 to 48 hours. The treatment of constipation with any medicine should only be in addition to a healthy lifestyle and diet.

2. What you need to know before you take Macrogol

Do not take Macrogol:

- 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 severe intestinal disease such as:
 - 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 conditions of unknown 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 Macrogol 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 Macrogol, talk to your doctor or pharmacist if you know that you have a swallowing disorder.

Avoid mixing Macrogol - PEG laxative 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 Macrogol

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with Macrogol, 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, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

Pregnancy and breast-feeding

Macrogol 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.

Macrogol 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. This medicine contains a small amount of a sugar called sorbitol, can be used if you are diabetic, or if you are on a galactose-free diet.

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

3. How to take Macrogol

Always take this medicine 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.

Adults and children over 8 years

- The recommended dose is one to two sachets per day, preferably taken as a single dose in the morning

- Start by taking one sachet each day and if needed increase to two sachets each day
- The daily dose can be adjusted according to the effect obtained and may range from one sachet every other day (especially in children) up to a maximum of two sachets per day
- Dissolve the contents of the sachet in a glass of water (at least 50 ml) immediately before use and drink the liquid

Please note:

- Macrogol usually takes 24 to 48 hours to work
- In the management of children with constipation, the duration of treatment with Macrogol should not exceed 3 months
- Improvement in the frequency of your bowel movements after taking Macrogol 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

If you take more Macrogol than you should

Taking too much Macrogol 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) due to fluid loss.

If you forget to take Macrogol

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, this medicine 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 (hypersensitivity) 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Macrogol

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 after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Macrogol contains

- The active substance is macrogol 4000
Each sachet contains 10 g of macrogol 4000
- The other ingredients
Saccharin Sodium and Orange Grape Fruit Flavour (contains orange oil, grape fruit oil, orange juice, citral, acetaldehyde, linalool, ethyl butyrate, alpha terpeniol, octonal, beta & gamma hexenol, maltodextrin, gum arabic, sorbitol (E420), butylated hydroxyanisole (E320)).

What Macrogol looks like and contents of the pack

Macrogol is white or almost white free flowing powder of waxy or paraffin like appearance with orange odour, packed in sachets containing 10, 20 and 30 pack sizes for the preparation of an oral solution

Not all pack sizes may be marketed

Marketing Authorisation Holder

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000
Malta

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This leaflet was last revised in 11/2023.



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