

leaflet: Information for the user

Macrogol 4000 10 g powder for oral solution in sachet

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, 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 your doctor, pharmacist or nurse. 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.

Note: For Rx; only ES

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 Macrogol 4000 is and what it is used for
2. What you need to know before you take Macrogol 4000
3. How to take Macrogol 4000
4. Possible side effects

5. How to store Macrogol 4000
6. Contents of the pack and other information

1. What Macrogol 4000 is and what it is used for

Macrogol 4000 belongs to a group of medicines called osmotic laxatives. It works by carrying water to your stool, which loosens and increases stool volume, helping to overcome sluggish bowels, working gradually within 24 to 48 hours

Macrogol 4000 is not absorbed into the bloodstream or broken down in the body. It is used for the treatment of constipation in adults and children aged 8 years and above.

Blue box for SE

It is used for the treatment of **temporary** constipation in adults and children aged 8 years and above.

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 4000

Do not take Macrogol 4000:

- if you are allergic 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) or abnormal dilation of the bowel
 - perforation of the bowel or risk of perforation of the bowel
 - intestinal obstruction or suspicion of intestinal obstruction or symptomatic narrowing of the bowel

- painful belly of unknown cause

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking < PRODUCT NAME >.

Without investigating the cause of constipation, Macrogol 4000 should not be taken on a continuous daily basis for an extended period of time. Medical advice should be sought in case the symptoms persist for more than 2 weeks or in case of persistent abdominal pain.

Cases of allergic reactions involving rash, hives and swelling of the face or throat 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 4000 and seek medical help immediately.

If you experience any of these symptoms you should stop taking Macrogol 4000 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

Children

Macrogol 4000 is not recommended for use in children below the age of 8 years.

Blue box for CZ

Children can use Macrogol 4000 only upon medical advice.

Other medicines and Macrogol 4000

Tell your doctor or pharmacist if you are taking, have recently taken or might take any **other medicines**, since the way this medicine works may influence the intestinal absorption of other medicines.

Pregnancy and breast-feeding

Macrogol 4000 can be taken during pregnancy and whilst 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 use machines have been performed.

Macrogol 4000 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 Macrogol 4000

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

Note: For Rx; only ES

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

The recommended dose is 1 to 2 sachets daily, preferably taken as a single dose in the morning. Macrogol 4000 is a powder that you dissolve in a glass of water (125 ml) and drink immediately.

In case the symptoms persist or get worst, a physician should be consulted.

Use in children and adolescents

In children 8 years and above, the recommended dose is 1 to 2 sachets daily, preferably taken as a single dose in the morning.

The daily dose should be adapted as required to produce regular soft stools and may range from one sachet every other day (especially in children) up to 2 sachets a day. If administered regularly, the frequency of bowel movements tends to be one movement per day.

Note: For Rx; only ES

The duration of the treatment should not exceed 3 months.

Also please note:

- Macrogol 4000 usually takes 24 to 48 hours to work
- Improvement in the frequency of your bowel movements after taking Macrogol 4000 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 4000 than you should

Taking too much Macrogol 4000 may cause diarrhoea, which usually disappears when treatment is stopped or the dose reduced. If you have lost a large amount of fluids by diarrhoea or vomiting, contact your doctor as you may require treatment to prevent loss of salts (electrolytes) due to fluid loss.

If you forget to take Macrogol 4000>

Take the next dose as soon as you remember.

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

If you do not feel better or if you feel worse after 14 days you must contact a doctor.

(Not applicable for Rx product.)

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

Whilst taking Macrogol 4000, if you develop any of the following symptoms **you should contact your doctor immediately**:

- Allergic reactions (rash, hives, swelling of the face or throat, breathing difficulties, faintness or collapse) (frequency not known, frequency cannot be estimated from the available data)

Other side effects

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

However if any of the following side effects gets serious, contact your doctor as soon as possible.

In adults:

Common (may affect up to 1 in 10 people):

- Abdominal pain
- Bloating
- Nausea
- Diarrhoea

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Urgent need to go to the toilet

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

- Passing gas

In children:

Common (may affect up to 1 in 10 people):

- Abdominal pain
- Diarrhoea

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Bloating
- Nausea

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

- Passing gas

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; please see <https://yellowcard.mhra.gov.uk>. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Macrogol 4000

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.

Do not store above 30°C. Store in its original container to protect from light.

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 4000 contains

- The active substance is macrogol 4000 (polyethylene glycol). Each sachet contains 10 g.
- The other ingredient(s) are magnesium citrate (anhydrous), cCitric acid (anhydrous), calcium citrate, acesulfame K, potassium chloride (with 0.9% silica colloidal, anhydrous), lemon-grapefruit flavour (contains natural lemon oil, liquid flavour grapefruit, powder flavour maracuja, powder flavour grenadine/raspberry, mannitol (E421), gluconolactone (E575), sorbitol (E420), anhydrous silica colloidal (E551)). See section 2 "PRODUCT NAME contains sorbitol (E420)".

What Macrogol 4000 looks like and contents of the pack

Macrogol 4000 is a white powder, free of large agglomerates, with an odour and taste of lemon, packed in an Aluminium / Paper sachet. The reconstituted solution is colourless & clear.

Pack sizes of 10 or 20 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PharOS - Pharmaceutical Oriented Services Ltd

Lesvou str. (end),

Thesi Loggos, Industrial Zone,

Metamorfossi Attikis

144 52

Greece

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

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{01/2015}>.