

PACKAGE LEAFLET: INFORMATION FOR THE USER

MACROGOL GRAPEFRUIT FLAVOUR 10g powder for oral solution

MACROGOL LEMON FLAVOUR 10g powder for oral solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take MACROGOL carefully to get the best results from it. 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.
- You must talk to a pharmacist or doctor if you do not feel better or if you feel worse after 2 weeks of treatment.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

There are two strengths available for use, 4g sachets for use in children from 6 months to 8 years (MACROGOL APPLE FLAVOUR) and 10g sachets for children from 8 years and adults (MACROGOL GRAPEFRUIT FLAVOUR and MACROGOL LEMON FLAVOUR), all will be referred to MACROGOL throughout the text.

MACROGOL contains a medicine called macrogol 4000. This belongs to a group of medicines called osmotic laxatives.

- MACROGOL is used to relieve constipation in adults and children 6 months and over. It carries water to your stools, which loosens and increases stool volume, helping to overcome sluggish bowels. It works only at the site of the problem, in the bowel, by a hydrating action to reactivate your normal rhythm.
- MACROGOL is a powder that you dissolve in water and drink.
- MACROGOL usually takes 24 to 48 hours to work.
- MACROGOL is not absorbed into the bloodstream or changed by the body.

Due to the size of each dose, MACROGOL 10g is not suitable for children under 8 years. Children aged 6 months to 8 years can use MACROGOL 4g only upon medical advice.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is “normal and regular” varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people; for others, it may happen more often.
- It happens when the normal muscle action in the bowel (large intestine) slows down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- Not drinking enough fluid (e.g. water)
- A diet with not enough fibre
- Loss of “tone” of the bowel muscles in older people
- Pregnancy
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body prompts you

2. What you need to know before you take MACROGOL

Do not take MACROGOL if you:

- are allergic (hypersensitive) to macrogol or any of the other ingredients of this medicine (listed in Section 6)
- have stomach pain without knowing the cause
- have a bowel condition called “ileus”
- have a blocked bowel (intestinal obstruction)
- have had a hole (perforation) in your bowel wall
- have inflammation of the bowel (small or large intestine), such as ulcerative colitis or Crohn’s disease

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 this medicine.

Warnings and precautions

If you regularly suffer from diarrhoea, check with your pharmacist or doctor before taking MACROGOL. This is especially important if you are elderly, have liver or kidney problems, or if you are taking water tablets (diuretics). This can lead to low sodium and potassium levels in your blood, or to dehydration.

Other medicines and MACROGOL

MACROGOL will not affect any other medicines that you take.

Pregnancy and breast-feeding

MACROGOL can be taken during pregnancy and whilst breast-feeding, but as with all medicines, ask for advice from your pharmacist or doctor beforehand.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of MACROGOL:

MACROGOL GRAPEFRUIT FLAVOUR: This product contains small amount of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

MACROGOL GRAPEFRUIT FLAVOUR contains 138mg of sucrose in 10g sachets.

This product can be used if you are diabetic.

3. How to take MACROGOL

Do not use MACROGOL without medical advice for more than two weeks because constipation can also be a symptom of serious diseases.

Long-term treatment should be always consulted with your doctor.

If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

Taking this medicine

Adults and children 8 years and over – 10g sachet

- Start by taking 1 sachet each day, dissolved in a glass of water.
- If needed increase to 2 sachets each day, taken as a single dose.
- Adjust your dose as needed. This may range from one sachet every other day (especially in a child) up to two sachets each day.
- Continue to take MACROGOL until your bowel movements return to normal.
- MACROGOL works gradually within 24 to 48 hours.
- It is best to take this medicine in the morning.
- Dissolve the powder from the sachet(s) in a glass of water, and then drink the whole contents of the glass.

Children should not be given this medicine for more than 3 months.

Children under the age of 8 years can use MACROGOL after receiving the advice of a health care professional who will evaluate the suitability of the product use.

Appearance of the product after reconstitution: Almost white to lightly yellowish opalescent solution.

If you take more MACROGOL than you should

Contact your doctor or pharmacist for advice.

If you forget to take MACROGOL

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

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

4. Possible side effects

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

The following side effects may happen with this medicine.

Adults

Stop taking MACROGOL and see a doctor straight away if you notice following side effects. You may need urgent medical treatment:

- Rash, itching and swelling of your face, or a more serious reaction causing difficulty in breathing or dizziness (anaphylactic shock). You may be having an allergic reaction to the medicine. This is very rare, and affects less than 1 in 10,000 people.
- Signs of a change in your body's fluid or electrolyte levels, such as swelling (mainly in the ankles), feeling fatigued, dehydration or increased thirst with headache, especially if you are elderly, or after suffering severe or prolonged diarrhoea.

Common (affect less than 1 in 10 people)

- Abdominal pain and swelling.
- Feeling sick (nausea).
- Diarrhoea. This should go away if you lower the dose or stop taking this medicine. Diarrhoea can cause soreness around the anus (back passage).

Uncommon (affect less than 1 in 100 people)

- Being sick (vomiting).
- Urgent need to go to the toilet (defecate).
- Bowel incontinence.

Children

Common (affect less than 1 in 10 people)

- Abdominal pain.
- Diarrhoea. This should go away if you lower the dose or stop taking this medicine. Diarrhoea can cause soreness around the anus (back passage).

Uncommon (affect less than 1 in 100 people)

- Being sick (vomiting).
- Bloating.
- Feeling sick (nausea).

Unknown (cannot be estimated from the available data)

- Hypersensitivity reactions (rash, itching and swelling of your face, or a more serious reaction causing difficulty in breathing or dizziness (anaphylactic shock).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store MACROGOL

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

MACROGOL does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

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

Each sachet contains 10g of macrogol 4000.

The other ingredients are Saccharin sodium dihydrate (E 954), Silica, colloidal anhydrous

MACROGOL GRAPEFRUIT FLAVOUR also contains grapefruit flavour powder (Sucrose, Aroma, Silica colloidal hydrated).

MACROGOL LEMON FLAVOUR also contains lemon powder (Maltodextrin, dried lemon juice).

What MACROGOL looks like and contents of the pack

MACROGOL GRAPEFRUIT FLAVOUR is an almost white to slightly yellowish powder with an odour and taste grapefruit, for making up into a drink.

MACROGOL LEMON FLAVOUR is an almost white to slightly yellowish powder with an odour and taste of lemon, for making up into a drink.

Size of packing

MACROGOL 10g sachets are available in a pack of 12 or 24 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer

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