

Package leaflet: Information for the user

Compound Macrogol 13.72 g powder for oral solution

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 has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice
- 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
- You must talk to a doctor if you do not feel better or if you feel worse.

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

The name of this medicine is Compound Macrogol 13.72 g powder for oral solution (referred to as Macrogol throughout the rest of this leaflet). It is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

Macrogol helps you to have a comfortable bowel movement even if you have been constipated for a long time. Macrogol also works in very bad constipation called faecal impaction.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MACROGOL

Do not take Macrogol if your doctor has told you that you have:

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

Warnings and precautions

When taking Macrogol you should continue to take plenty of fluids. The fluid content of Macrogol should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking Macrogol for faecal impaction.

Other medicines and Macrogol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Macrogol.

You should not take any other medicines by mouth together with Macrogol and for one hour before and for one hour after taking Macrogol.

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 taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking Macrogol.

Driving and using machines

Macrogol does not affect your ability to drive or use machines.

Macrogol contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Macrogol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE MACROGOL

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

Dissolve the content of each sachet in 125ml (¼ pint) of water immediately before use and drink.

Constipation:

A dose of Macrogol is 1 sachet dissolved in 125 ml (¼ pint) of water. Take this 1–3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Macrogol for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Macrogol is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (¼ pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

(Continued overleaf)

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Macrolog solution is clear or slightly hazy, then drink it. If you are taking Macrolog for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with Macrolog usually lasts for about 2 weeks. If you need to take Macrolog for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take Macrolog for longer than 2 weeks. If you need to take Macrolog for longer, please see your doctor.

Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Macrolog can be for up to 3 days.

If you take more Macrolog than you should:

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking Macrolog and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Macrolog:

Take the dose as soon as you remember to take it.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately and stop taking Macrolog if you:

- Get a serious allergic reaction with causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and may have mild diarrhoea when starting to take Macrolog. These side effects generally get better if you reduce the amount of Macrolog you take.

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 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 Macrolog after the expiry date which is stated on the sachet and carton.

Store below 25°C. Store in the original package in order to protect from moisture.

Once you have made up Macrolog in water, use immediately.

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 Macrolog contains

Each 13.72g sachet of Macrolog contains the following:

Macrolog 3350	13.125 g
Sodium Chloride	0.3507 g
Sodium Bicarbonate	0.1785 g
Potassium Chloride	0.0466 g

Macrolog also contains lemon flavour and acesulfame potassium as a sweetener.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

Sodium Chloride	65 millimoles/litre
Potassium Bicarbonate	5.4 millimoles/litre
	17 millimoles/litre

What Macrolog looks like and contents of the pack

Macrolog is a white powder.

Macrolog is available in a box of 30 sachets.

Marketing Authorisation Holder and Manufacturer

Manx Healthcare Ltd
Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ,
United Kingdom

Other formats

To request a copy of this leaflet in Braille, large print or audio, please call 01926 482511.

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