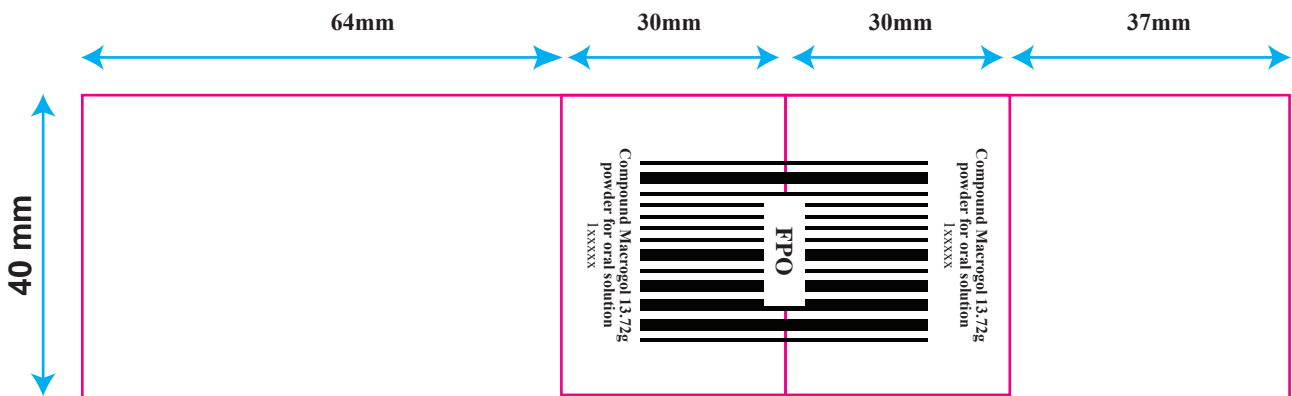


Artwork for Submission Purpose: UK Market



Package leaflet: Information for the patient

Compound Macrogol 13.72 g powder for oral solution

macrogol 3350, sodium chloride, sodium bicarbonate, potassium chloride

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.

What is in this leaflet

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

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

The name of this medicine is Compound Macrogol 13.72g powder for oral solution. It is a laxative for the treatment of chronic constipation in adults, adolescents and elderly and for the treatment of very bad constipation (called faecal impaction).

It is not recommended for children below 12 years of age.

Compound Macrogol helps you to have a comfortable bowel movement even if you have been constipated for a long time.

2. What you need to know before you take Compound Macrogol

Do not take Compound Macrogol:

- if you are allergic to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients in this medicine (listed in section 6).
- if you have a blockage in the intestine (gut obstruction, ileus)
- if you have a perforated gut wall
- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

Talk to your doctor or pharmacist before taking Compound Macrogol.

If you develop side effects such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems you should stop taking Compound Macrogol and contact your doctor immediately.

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

Avoid mixing Compound Macrogol 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.

Compound Macrogol contains 0.6213 mmol (24.230 mg) of potassium per sachet. This should be taken into consideration if the patient takes more than one sachet daily and has reduced kidney function or is on a controlled potassium diet.

Heart conditions

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

Children

This medicine is not recommended for children below 12 years of age.

Other medicines and Compound 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 Compound Macrogol.

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

Compound Macrogol with food and drink

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

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.

Compound Macrogol can be taken during pregnancy and whilst breast-feeding.

Driving and using machines

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

Compound Macrogol contains sodium

Compound 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 Compound Macrogol

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

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

Chronic constipation:

For adults, adolescents and the elderly the recommended dose is 1 sachet, 1–3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Compound Macrogol for faecal impaction, your doctor must check to confirm that you have this condition.

For adults, adolescents and the elderly the recommended dose is 8 sachets a day. All the 8 sachets should be taken within 6 hours, and for up to 3 days if required. If you have a heart conditions do not take more than 2 sachets per one hour.

Method of Administration

- Open the sachet and pour the contents into a glass.
- Add ½ glass (about 125ml) of water.
- Stir well until all the powder has dissolved and the Compound Macrogol solution is clear or slightly hazy, then drink it.

If you are taking Compound Macrogol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment Chronic constipation:

Treatment with Compound Macrogol usually lasts for about 2 weeks. If you need to take Compound Macrogol for longer, please see your doctor.

160 x 340 mm

Font: Times New Roman 9 pt

Front Page



Compound Macrogol 13.72 g powder for oral solution

Packinsert - SPUK - Submission

Dimension: 160 x 340 mm

MFG Location: KRSG

Market: SPUK

Version: 01

Date: 29.02.2024

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 Compound Macrogol for longer than 2 weeks.

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

Faecal impaction:

Treatment with Compound Macrogol can be for up to 3 days.

If you take more Compound Macrogol than you should

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

If you forget to take Compound Macrogol

Take the dose as soon as you remember.

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 Compound Macrogol if you:

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

Other side effects include:

- indigestion
- stomach pains
- stomach rumbles
- mild diarrhoea (when starting taking Compound Macrogol)
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom)
- swollen stomach
- wind

These side effects generally get better if you reduce the amount Compound Macrogol you take.

- allergic reactions which may cause a skin rash (hives), 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.

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

- change in your body's fluid or electrolyte levels (low levels of potassium, low levels of sodium)

If any of the above become serious or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Compound 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 sachet. The expiry date refers to the last day of that month.

Unopened sachet: No special storage conditions.

Once you have made up Compound Macrogol in water, if you cannot drink it straight away keep it covered and, in the fridge, (2 – 8°C). Throw away any solution not used within a 24 hour period.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Compound Macrogol contains

Each 13.72 g sachet of Compound Macrogol contains the following:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium bicarbonate	178.5 mg
Potassium chloride	46.6 mg

The other ingredients are Acesulfame potassium and lemon flavor.

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 Compound Macrogol looks like and contents of the pack

Compound Macrogol is a white crystalline powder which comes in single dose sachets. Boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets are available.

Not all pack sizes will be marketed.

Marketing Authorisation holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford,
WD18 9SS,
United Kingdom.

This leaflet was last revised in 02/2024.



1XXXX



Compound Macrogol 13.72 g powder for oral solution

Packinsert - SPUK - Submission

Dimension: 160 x 340 mm

MFG Location: KRSG

Market: SPUK

Version: 01

Date: 29.02.2024