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## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Macrogol Compound Powder for Oral Solution

Macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride

#### 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 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 after 14 days.

#### What is in this leaflet

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

#### 1. WHAT MACROGOL COMPOUND IS AND WHAT IT IS USED FOR

Macrogol Compound is a laxative used for the treatment of long term constipation. It is not recommended for children below 12 years of age. Macrogol Compound contains macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride. Macrogol 3350 makes your faeces softer and easier to pass, giving you relief from constipation. The electrolytes (salts) help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MACROGOL COMPOUND

##### Do not take Macrogol Compound:

- if you are allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients of this medicine (listed in section 6)
- if you have a perforated gut (bowel) wall
- if you have a blockage in your intestine (gut obstruction, ileus)
- if you have severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon.

If any of these apply to you, please talk to your doctor or pharmacist for further advice.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Macrogol Compound if you:

- have epilepsy or a history of convulsions
- have heart failure, severe kidney problems or are taking blood pressure medicine

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

If you experience sudden abdominal pain or rectal bleeding when taking Macrogol Compound for bowel preparation, contact your doctor or seek medical advice immediately.

If you experience (blood) vomiting followed by sudden chest, neck or abdominal pain, difficulty swallowing or difficulty breathing when taking Macrogol Compound, stop taking this medicine and promptly contact your doctor.

Avoid mixing Macrogol Compound (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 Compound

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. Some medicines e.g. anti-epileptics may not work as effectively during use with Macrogol Compound. You should not take any other medicines by mouth together with Macrogol Compound and for one hour before and for one hour after taking Macrogol Compound. If you need to thicken fluids in order to swallow them safely, Macrogol Compound may counteract the effect of the thickener.

##### Pregnancy and breast-feeding

Macrogol Compound 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

Macrogol Compound has no effect on your ability to drive or use machinery.

##### Macrogol Compound contains sodium and sorbitol (E420)

This medicine contains 187 mg sodium (main component of cooking salt) in each sachet. This is equivalent to 9% of the recommended maximum daily dietary intake of sodium for an adult. 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.

This medicine contains up to 50 mg sorbitol in each sachet.

##### Potassium content

This medicine contains potassium, less than 1 mmol (39 mg) per sachet, i.e. essentially 'potassium-free'.

#### 3. HOW TO TAKE MACROGOL COMPOUND

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

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

Dissolve the content of each sachet in 125ml (1/4 pint) of water and drink.

##### Adults, children (aged 12 years and above) and the elderly:

The recommended dose for constipation is one sachet taken one to three times daily.

##### How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or a quarter pint of water to the glass. Stir well until the powder has dissolved and then drink it.

##### Duration of treatment

This course of treatment for constipation should not normally last longer than 2 weeks. If you need to take Macrogol Compound 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 Macrogol Compound for longer than 2 weeks. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

##### If you take more Macrogol Compound than you should

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

##### If you forget to take Macrogol Compound

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

##### If you stop taking Macrogol Compound

To get the most benefit from Macrogol Compound, always finish the course of treatment according to the directions in this package leaflet. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist.

You must contact a doctor if your symptoms worsen or do not improve after 14 days.

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.

##### If you experience any of the following side effects, stop taking Macrogol Compound and see a doctor immediately:

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

##### 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
- abdominal (stomach) pain
- mild diarrhoea (when starting to take Macrogol Compound, this usually stops if you reduce the number of sachets you take)
- nausea (feeling sick)
- indigestion
- vomiting
- swelling of your abdomen (feeling bloated)
- stomach rumbling
- flatulence (wind)
- soreness of the anus (bottom)
- oesophageal rupture due to vomiting frequency not known.

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://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 COMPOUND

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

Unopened sachets should not be stored above 25°C.

Do not use this medicine if you notice that any of the sachets are damaged.

Reconstituted Macrogol Compound solution can be covered and stored in the refrigerator (2°C to 8°C) and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

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 Compound contains

The active substances are macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride.

Each sachet contains:	
macrogol 3350	13.125 g
sodium chloride	0.3507 g
sodium hydrogen carbonate	0.1785 g
potassium chloride	0.0466 g

The other ingredients are colloidal anhydrous silica, saccharin sodium, orange flavour (Orange flavouring contains: flavouring substances and preparations, maltodextrin, acacia gum (E414), alpha-tocopherol (E307)) and lemon lime flavour (Lemon lime flavouring contains: flavouring preparations, maltodextrin, mannitol (E421), gluconolactone (E575), sorbitol (E420), acacia gum (E414), colloidal anhydrous silica (E551)).

##### What Macrogol Compound looks like and contents of the pack

Macrogol Compound is a white powder.

Each sachet contains 13.8 g of powder and is packed in cartons containing 2, 6, 8, 10, 20, 30, 50, 60 (2x30) and 100 (2x50) sachets.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder

Ennogen IP Ltd.  
Unit G4, Riverside Industrial Estate,  
Riverside Way, Dartford, DA1 5BS,  
UK.

##### Manufacturer

Hermes Pharma Ges.m.b.H.  
Allgäu 36, 9400 Wolfsberg, Austria

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