

## **Package leaflet: Information for the patient**

### **Macrolief 13.8g sachet, powder for oral solution**

macrogol 3350 / sodium chloride / sodium hydrogen carbonate / 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 Macrolief is and what it is used for
2. What you need to know before you take Macrolief
3. How to take Macrolief
4. Possible side effects
5. How to store Macrolief
6. Contents of the pack and other information

#### **1. What Macrolief is and what it is used for**

Macrolief is a laxative used for the treatment of constipation (especially if constipation lasts a long time) in adults, adolescents and elderly. It is not recommended for children below 12 years of age. It is also used to treat a build up of hard faeces in your bowel which may be a result of long-term constipation (this is known as faecal impaction).

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 Macrolief**

##### **Do not take Macrolief**

- if you are allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients in 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.

Talk to your doctor or pharmacist before taking this medicine.

##### **Warnings and precautions**

Before taking with Macrolief to treat faecal impaction, you should have this condition confirmed by your doctor.

If you have heart condition and you take product for faecal impaction, follow the special instructions in section 3.

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 Macrolief, and contact your doctor immediately.

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

### **Children**

Do not give this medicine to children below 12 years of age.

### **Other medicines and Macrolief**

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 Macrolief. Therefore, other medicines should not be taken orally for one hour before and for one hour after taking this medicine.

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

### **Pregnancy and breast-feeding**

Macrolief can be taken during pregnancy and whilst breast-feeding. If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

This medicine does not affect your ability to drive or use machines.

### **Macrolief contains sodium, sorbitol and potassium**

This medicine contains 188 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 9.4% of the recommended maximum daily dietary intake of sodium for an adult.

The maximum recommended daily dose of this medicine when used for constipation contains 564 mg sodium (found in table salt). This is equivalent to 28.2% of the recommended maximum daily dietary intake for sodium.

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

The maximum recommended daily dose of this medicine when used for faecal impaction contains 1504 mg sodium (found in table salt). This is equivalent to 75.2% of the adult recommended maximum daily dietary intake for sodium.

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

This medicine contains 0.6 mmol (or 24.4 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

The lemon lime flavour in this medicine contains 0.8 mg sorbitol (E420) in each sachet.

## **3. How to take Macrolief**

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

### **Constipation**

A dose of Macrolief 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.

Treatment with this medicine usually lasts for about 2 weeks. If you need to take this medicine 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 this medicine for longer than 2 weeks. If you need to take this medicine 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**

Before you take this medicine for faecal impaction, it should be confirmed that you have this condition. A dose of 8 sachets a day of Macrolief is needed for the treatment of faecal impaction. Each sachet is 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.

### 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 all the powder has dissolved and the solution is clear or slightly hazy, then drink it.

If you are being treated for faecal impaction, you can dissolve the contents of all eight sachets together in a large container (in one litre of water).

This medicine should be taken orally.

### **Children**

Do not give this medicine to children below 12 years of age.

### **If you take more Macrolief than you should**

This can cause severe pain and bloated stomach, vomiting (sickness) or diarrhoea. Excessive diarrhoea can lead to dehydration. If this occurs, stop taking this medicine and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

### **If you forget to take Macrolief**

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.

### **If you experience any of the following side effects, stop taking Macrolief, and see your doctor immediately:**

- If you get signs of an allergy, such as a rash, itching, reddening of the skin, shortness of breath, difficulty in breathing, or swelling of the face, lips, tongue or throat.
- If you get signs of a change in your body's fluid or electrolyte levels (salts levels), such as swelling (mainly in the ankles), feeling weak, dehydration, increasingly tired or increased thirst with headache. These symptoms may be a sign that the potassium levels in your blood are higher or lower than normal.

Other side effects include:

- swollen hands, feet or ankles
- headaches
- indigestion, stomachache or rumbles
- feel bloated, suffer from wind, feel sick or vomit
- soreness of the anus (bottom)
- diarrhoea (when starting to take this medicine)
- change in your body's fluid or electrolyte levels (low levels of sodium).

These side effects generally get better if you reduce the amount of Macrolief you take.

The frequencies of these side effects are not known (cannot be estimated from the available data).

### **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: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). For Malta, you can also report side effects via the ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Macrolief**

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 25°C.

Reconstituted Macrolief solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within twenty-four hours. After twenty-four hours, any unused solution should be discarded.

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

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 Macrolief contains**

The active substances are:

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 flavour contains: flavouring substances and flavouring preparations, maltodextrin, acacia gum (E414), alpha-tocopherol (E307)) and lemon lime flavour (lemon lime flavour contains: natural lemon oil, natural powder flavour lemon, powder flavour lime, maltodextrin, mannitol (E421), gluconolactone (E575), sorbitol (E420), acacia gum (E414), colloidal anhydrous silica (E551)).

#### **What Macrolief looks like and contents of the pack**

Macrolief is a white crystalline powder.

The sachet is composed of PAP/ALU/PE.

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 and Manufacturers**

### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

### **Manufacturers**

Klocke Pharma-Service GmbH, Strassburger Strasse 77, 77767 Appenweier, Germany.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Hermes Pharma GmbH, Schwimmschulweg 1a, 9400 Wolfsberg, Austria.

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Macrogol + elektrolytes Sandoz poeder voor drank
Denmark	Gangiden
Germany	Macrogol HEXAL plus Elektrolyte Pulver zur Herstellung einer Lösung zum Einnehmen
Ireland	Macrolief 13.8g sachet, powder for oral solution
Italy	MACROGOL SANDOZ
Malta	Macrolief 13.8g sachet, powder for oral solution
The Netherlands	Macrogol en elektrolyten Sandoz 13,8g, poeder voor drank
Portugal	Actolaxan
Spain	Atolaxant 13,7 g polvo para solución oral
Sweden	Laxiriva pulver till oral lösning, i dospåse
United Kingdom	Compound Macrogol 13.8g Powder for Oral Solution

**This leaflet was last revised in 11/2021.**