

## Package leaflet: Information for the user

### Movilief 13.7g Powder for Oral Solution, Sachet

**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 or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 14 days for chronic constipation, or after 3 days for faecal impaction.
- 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 Movilief is and what it is used for
2. What you need to know before you take Movilief
3. How to take Movilief
4. Possible side effects
5. How to store Movilief
6. Contents of the pack and other Information

#### 1. What Movilief is and what it is used for

The name of this medicine is Movilief 13.7g powder for oral solution.

- It is a laxative for the treatment of chronic constipation in adults, children (aged 12 years and above) and the elderly.
- It helps you to have a comfortable bowel movement even if you have been constipated for a long time. It also works in very bad constipation called faecal impaction (complete severe constipation).

#### 2. What you need to know before you give Movilief

##### **DO NOT take Movilief if you:**

- are allergic to any of the ingredients of this medicine (listed in section 6).
- have a perforated gut wall.
- have a blockage in your intestine (gut obstruction, ileus) for example by paralysis of the intestine.
- have severe inflammatory bowel disease like 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

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 Movilief and contact your doctor immediately.

#### Other medicines and Movilief

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 effectively during use with Movilief. Tell your doctor about any other medicines you are taking. When taking large volumes of Movilief (e.g. for faecal impaction), you should not take other medicines within one hour of taking Movilief.

#### Pregnancy and breast-feeding

**Movilief** 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 for advice before taking this medicine.

RMS' comment:

The MAH is requested to amend this section in line with the comments on SPC.

### **Driving and using machines**

Movilief has no effect on the ability to drive or use machines.

**Movilief contains 0.68mmol (26mg) of potassium per sachet.** This should be taken into consideration if you take more than one sachet daily and you have reduced kidney function, or if you are on a controlled potassium diet.

**Movilief contains 8.13mmol (187mg) of sodium per sachet.** This should be taken into consideration if you are on a controlled sodium diet.

### **3. How to take Movilief**

Always take this medicine exactly as described in this leaflet or 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 (Constipation for a long time)**

Recommended dose for adults and children above 12 years: 1 sachet one to three times daily, depending on the severity of your constipation.

The dose can be adjusted down to the lowest effective dose after a couple of days.

### **Faecal Impaction (Complete severe constipation)**

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

Recommended dose for adults and children above 12 years: 8 sachets daily. The 8 sachets should be taken within a 6 hour period each day for up to 3 days if required.

### **Children below 12 years of age**

This medicine is not recommended. Other forms of this medicine may be more suitable.

### **Patients with renal insufficiency**

No dosage change is necessary for treatment of chronic constipation or faecal impaction.

### **Patients with a heart condition**

Do not take more than 2 sachets in one hour.

### **Method of Administration**

Open the sachet and pour the contents into a glass. Add 125ml or ¼ 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 it may be easier to dissolve all 8 sachets in 1 litre of water. The ready to use solution should be kept covered in the refrigerator for not more than 24 hours.

### **Duration of treatment**

Constipation: Treatment with Movilief usually lasts for about 2 weeks. If you need to take Movilief 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 Movilief for longer than 2 weeks. If you need to take Movilief 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 Movilief can be for up to 3 days.

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

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

#### **If you forget to take Movilief**

Take the dose as soon as you remember and then continue as before. 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.

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

- A serious allergic reaction which causes difficulty in breathing or dizziness, or swelling of the face, lips, tongue or throat.
- Signs of an allergy, such as a rash, itching or shortness of breath.
- 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. These symptoms may be a sign that the potassium levels in your blood are higher or lower than normal.

The following side effects have also been reported:

##### **Common (may affect up to 1 in 10 people)**

- Stomach rumbling, swollen stomach or stomach pain, suffering from wind
- Vomiting, feeling sick, indigestion
- Sore anus (bottom)

If you experience mild diarrhoea when you start to take Movilief your condition will generally get better if you reduce the amount of Movilief you take.

##### **Very rare (may affect up to 1 in 10,000 people)**

- Hives, reddening of the skin or a nettle rash
- Swelling of the hands, feet or ankles

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

- Headaches.

##### 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 HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Movilief**

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.

Unopened sachet: No special storage conditions.

Once you have made up Movilief in water, if you cannot drink it straight away keep it covered and store in a refrigerator (2°C – 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 medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Movilief contain**

The active substances are macrogol 3350 (13.125g), sodium chloride (350.7mg), sodium hydrogen carbonate (178.5mg) and potassium chloride (46.6mg).

The other ingredients are lemon flavour and acesulfame potassium (E950) as a sweetener. The lemon flavour contains the following ingredients: acacia gum (E414) and flavouring.

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

Movilief is a white powder packed in sachets. It is available in boxes of 10, 20, 30, 40, 50, 60, 80, 90, 100, 120, 140, 160, 180 or 200 sachets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder is:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

The manufacturer is:

Chanelle Medical, Loughrea, Co. Galway, Ireland

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Centrafarm Services B.V., Nieuwe Donk 9, NL-4879 AC Etten-Leur, The Netherlands

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

Austria:	Clericol Pulver zur Herstellung einer Lösung zum Einnehmen
Belgium	Macrogol + Electrolytes EG 13,7g poeder voor drank
Germany:	Macrogol STADA 13,7 g Pulver zur Herstellung einer Lösung zum Einnehmen
Ireland:	Movilief 13.7g powder for oral solution
Italy:	Macrogol EG 13,7g polvere per soluzione orale
Luxembourg:	Macrogol + Electrolytes EG 13,7g poudre pour solution buvable
Netherlands:	Macrogol en electrolyten CF 13,7 g, poeder voor drank

**This leaflet was last revised in May 2014.**