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Package Leaflet: Information for the patient

MOVICOL[®]

13.8g sachet, powder for oral solution

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Movicol is and what it is used for

The name of this medicine is Movicol 13.8g sachet, powder for oral solution. 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.

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

2. What you need to know before you take Movicol

Do not take Movicol 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 Movicol (listed in section 6).

Warnings and precautions

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

Heart conditions

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

Other medicines and Movicol

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 Movicol.

Pregnancy and breast feeding

Movicol 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 Movicol.

Driving and using machines

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

3. How to take Movicol

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.

Constipation:

A dose of Movicol is 1 sachet dissolved in 125 ml (1/4 pint) of water. Take this 1 –3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Movicol for faecal impaction, it should be confirmed that you have this condition. A dose of 8 sachets a day of Movicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (1/4 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 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol solution is clear or slightly hazy, then drink it. If you are taking Movicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

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

If you take more Movicol than you should:

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

If you forget to take Movicol:

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 Movicol 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:

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

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, HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Movicol

Keep this medicine out of the sight and reach of children.

Do not use Movicol after the expiry date which is stated on the sachet and carton.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Once you have made up Movicol 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 6 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 Movicol contains

Each 13.8g sachet of Movicol contains the following:

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

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

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

Sodium	65 mmol/l
Chloride	53 mmol/l
Potassium	5.4 mmol/l
Bicarbonate	17 mmol/l

What Movicol looks like and contents of the pack

Movicol is a powder for oral solution.

Movicol is available in boxes of 30 sachets.

Parallel Product Authorisation Holder:

Novalus Healthcare Ltd.
Stephenstown Industrial Park,
Balbriggan,
Co. Dublin,
Ireland.

Manufacturer:

Laboratories Macors, Rue des Caillottes, Z.I. Plaine des Isles, 89000 Auxerre, France.

Repackaged by:

Millmount, Block 7, City North Business Campus, Stamullen Hall, Stamullen, Co. Meath, Ireland.

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

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Belgium MOVICOL
Denmark MOVICOL
Germany MOVICOL V
Finland MOVICOL
France MOVICOL
Iceland MOVICOL
Ireland MOVICOL
Italy MOVICOL 13,8 g polvere per soluzione orale
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PARALLEL PRODUCT AUTHORISATION NUMBER:

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