PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

MOVICOL® Powder for Oral Solution

Your medicine is available using the name Movicol Powder for Oral Solution but will be referred to as Movicol Powder throughout the leaflet.

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.

What is in this leaflet:

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

What Movicol Powder is and what it is used for

The name of this medicine is Movicol Powder. 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 Powder helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol Powder also works in very bad constipation called faecal impaction.

2. What you need to know before you take Movicol Powder

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

Warnings and precautions

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

Heart conditions

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

Other medicines and Movicol Powder

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 Powder.

Pregnancy and breast-feeding

Movicol Powder can be taken during pregnancy and whilst breast-feeding. If you are pregnant, trying to become pregnant or breast-feeding, ask your pharmacist or doctor for advice before taking Movicol Powder.

Driving and using machines

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

3. How to take Movicol Powder

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 Powder 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 Powder 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 1/4 pint of water to the glass. Stir well until all the powder has dissolved and the Movicol Powder solution is clear or slightly hazy, then drink it. If you are taking Movicol Powder for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment: Constipation:

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

If you take more Movicol Powder than you should:

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

If you forget to take Movicol Powder:

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

- Keep all medicines out of the sight and reach of children.
- Sachet: do not store above 25°C.
- Solution: store at 2-8°C (in a refrigerator and covered).
- Discard any solution not used within 6 hours.
- Do not use after the expiry date printed on the carton or sachet.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If your doctor tells you to stop taking the medicine, please take them back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to. If the powder becomes discoloured or shows signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Movicol Powder contains

Each 13.8g sachet contains:

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

Movicol Powder also contains citrus flavour, and acesulfame K (E950) as a sweetener.

Movicol Powder is a free flowing white, almost odourless powder for oral solution which dissolves in water to give a colourless solution with an odour of lemons.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

Sodium: 65 millimoles/litre
 Chloride: 53 millimoles/litre
 Potassium: 5.4 millimoles/litre
 Bicarbonate: 17 millimoles/litre

What Movicol Powder looks like and contents of the pack

Movicol Powder is available in boxes of 20 sachets. Each sachet contains 13.8 grams of Movicol Powder.

Manufacturer

Manufactured by: Norgine Limited, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, UK.
Or

LABORATOIRES MACORS, Rue des Caillottes, Z.I. Plaine des Isles, 89000 AUXERRE, France.

SOPHARTEX, 21 Rue du Pressoir, 28500 VERNOUILLET, France

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

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