

Package leaflet: Information for the patient

MOVICOL® Ease 13.7g 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.

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

1. What Movicol Ease is and what it is used for

The name of this medicine is Movicol Ease 13.7g powder for oral solution but will be referred to as Movicol Ease throughout the rest of this leaflet. It is a laxative for the relief of occasional constipation in adults. It should not be used in children or adolescents under the age of 18 years.

Speak to your pharmacist or doctor about alternative Movicol medicinal products that are available for children and adolescents under the age of 18 years.

Movicol Ease helps you to have a comfortable bowel movement when you have an episode of constipation.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is "normal and regular" varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

• Constipation is an occasional problem for some people. For others, it may happen more often.

• It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Not drinking enough fluids
- Loss of 'tone' of the bowel muscles in older people
- Pregnancy



- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally "off colour". Sometimes, it causes headaches. It is recommended to use changes in diet to control constipation before using this medicine. These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body tells you

Overuse of laxatives may damage your health by:

• Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.

• Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.

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

Do not take Movicol Ease if your doctor has told you that you have:

- a blockage in your intestine (gut obstruction, paralysis of the intestine (ileus))

- a small hole in your gut wall (a perforated gut wall)
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon
- an allergy to the active substances of Movicol Ease (listed in section 6).

Warnings and precautions

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

Other medicines and Movicol Ease

Before taking Movicol Ease, 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 Ease.

You should not take any other medicines by mouth together with Movicol Ease and for one hour before and for one hour after taking Movicol Ease.

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

Pregnancy and breast feeding

Movicol Ease 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 Ease.

Driving and using machines

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

Movicol Ease contains sodium

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.

Movicol Ease contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Movicol Ease

Adults aged 18 years and over: 1-3 sachets daily.

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

Dissolve one sachet in 125ml (1/4 pint) of water, 1-3 times per day.

This should be taken in divided doses throughout the day, according to the severity of your constipation.

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 Ease solution is clear or slightly hazy, then drink it.

Duration of treatment:

Movicol Ease should not be used for more than 5 days. If your constipation needs treatment for longer than 5 days, consult your doctor or pharmacist. When regular bowel movements return, you can use fewer doses in a day and usually treatment can be stopped.

If you have abdominal pain that does not get better, or you have blood in your bowel movements, you should consult your doctor.

If you take more Movicol Ease than you should:

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

If you forget to take Movicol Ease:

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 Ease if you:

• Get a serious allergic reaction which causes difficulty in breathing or dizziness, 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 Ease. These side effects generally get better if you reduce the amount of Movicol Ease you take.

If you develop any symptoms indicating shifts of fluids/electrolytes (e.g. swelling, shortness of breath, increasing fatigue, dehydration or heart failure (symptoms include breathlessness after activity or at rest, swollen ankles and legs, feeling tired most of the time and find exercise exhausting), you should speak to your doctor and immediately stop taking Movicol Ease.

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 Yellow Card Scheme Website: <u>www.mhra.gov.uk/yellowcard</u> 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 Movicol Ease

Keep this medicine out of the sight and reach of children. Do not use Movicol Ease after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once you have made up Movicol Ease in water, if you cannot drink it straight away keep it covered and in the fridge $(2^{\circ}C - 8^{\circ}C)$. 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 Ease contains

Each 13.7 g sachet of Movicol Ease contains the following:

Macrogol 3350 13.125 g



Sodium Chloride0.3508 gSodium Hydrogen Carbonate0.1786 gPotassium Chloride0.0502 g

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
Hydrogen Carbonate	17 millimoles/litre

What Movicol Ease looks like and contents of the pack

Movicol Ease is a white powder.

Movicol Ease is available in tubular (stick-pack) sachets.

Movicol Ease is available in boxes of 10 and 20 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Norgine Pharmaceuticals Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

Manufacturer:

Norgine Limited, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, U.K. Or SOPHARTEX, 21 rue du Pressoir, 28500 VERNOUILLET, France Or Norgine B.V., Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

This leaflet was last revised in 02/2024.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print or Braille please ring 0800 198 5000.