

Package Leaflet: Information for the patient

Movicol oral solution in sachet

Macrogol 3350, Sodium Chloride, Sodium Hydrogen Carbonate, Potassium Chloride

[For medicines available on prescription]

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.

[For medicines available without a prescription]

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 have 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 within 2 weeks or if you feel worse.

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 oral solution in sachet. It is a laxative for the treatment of constipation in adolescents, adults and older people. 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.

You must talk to a doctor if you do not feel better within 2 weeks or if you feel worse.

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 (a hole in the 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.

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

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

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.

Movicol 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 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

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

Drink Movicol directly from the sachet. There is no need to dilute it with water.

To maintain good health, including a healthy bowel, it is recommended to drink sufficient amounts of fluids (generally 2.0 to 2.5 litres daily).

[For medicines available on prescription only:]

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

[For medicines available without prescription:]

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Constipation:

A dose of Movicol is one 25 mL sachet. Take 1–3 sachets a day in divided doses according to your response to Movicol.

Faecal impaction:

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

Eight sachets a day of Movicol are needed for the treatment of faecal impaction. The 8 sachets should be taken within 6 hours. If you have a heart condition, do not take more than 2 sachets in any one hour.

It is recommended to drink an extra 1.0 litre of fluid per day if you have severe constipation (called faecal impaction).

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.

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 that you take of this medicine.

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 national reporting system listed in Appendix V](#). 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. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not refrigerate or freeze.

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 25 mL sachet of Movicol contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium Chloride	0.3508 g
Sodium Hydrogen Carbonate	0.1786 g
Potassium Chloride	0.0502 g

Movicol also contains sucralose, purified water and strawberry banana flavouring which contains natural flavouring substances (including extracts from strawberry and banana fruit), flavouring preparations (including celery) and propylene glycol.

Each 25 mL sachet gives the equivalent of:

Sodium	8.125 mmol
Chloride	6.675 mmol
Potassium	0.675 mmol
Hydrogen Carbonate	2.125 mmol

What Movicol looks like and contents of the pack

Movicol is a clear, colourless to light yellow liquid.

Movicol is available in boxes of 10, 20, 30 and 50 sachets.
Not all pack sizes may be marketed.

Marketing authorisation holder:

To be completed nationally.

Manufacturer:

The manufacturer is Norgine Pharma, 29 Rue Ethé Virton, 28100 Dreux Cedex, France

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium	MOVICOL Unidose
Finland	MOVICOL Ready to Take
Germany	Macrogol Norgine trinkfertig Lösung zum Einnehmen im Beutel
Ireland	MOVICOL Ready to Take
Italy	MOVICOL
Portugal	MOVICOL
Spain	MOVICOL solución oral en sobre
Sweden	Movicol oral lösning i dospåse

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