



Package leaflet: Information for the patient

Movicol® Plain 13.7g sachet, 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.

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

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

The name of this medicine is Movicol Plain 13.7g 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 Plain helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol Plain also works in very bad constipation called faecal impaction.

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

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

- a blockage in your intestine (gut obstruction, paralysis of the intestine (ileus))
- 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 Plain (listed in section 6).

Warnings and precautions

When taking Movicol Plain 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 Plain for faecal impaction

Other medicines and Movicol Plain

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 Plain.

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

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

Pregnancy and breast feeding

Movicol Plain 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 Plain.

Driving and using machines

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

Movicol Plain 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 Plain 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 Plain

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

Dissolve the content of each sachet in 125 ml (1/4 pint) of water and drink.

Constipation:

A dose of Movicol Plain 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 Plain for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Movicol Plain is needed for the treatment of faecal impaction. Each sachet dissolved in 125 ml (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 Plain solution is clear or slightly hazy, then drink it. If you are taking Movicol Plain for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

**Duration of treatment:****Constipation:**

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

If you take more Movicol Plain than you should:

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

If you forget to take Movicol Plain:

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 Plain 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 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 Plain. These side effects generally get better if you reduce the amount of Movicol Plain 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 HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.



5. How to store Movicol Plain

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

Do not use Movicol Plain 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 Plain in water, if you cannot drink it straight away keep it covered and in the fridge (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 Movicol Plain contains

Each 13.7 g sachet of Movicol Plain contains the following:

Macrogol 3350	13.125 g
Sodium Chloride	0.3508 g
Sodium Hydrogen Carbonate	0.1786 g
Potassium Chloride	0.0502 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 Plain looks like and contents of the pack

Movicol Plain is available in rectangular sachets and tubular (stick-pack) sachets.

Movicol Plain is a white powder.

Movicol Plain is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets. Not all sachets and pack sizes may be marketed.

Marketing authorisation holder:

Norgine Healthcare B.V., Antonio Vivaldistraat 150, 1083 HP Amsterdam, Netherlands



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 medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	MOVICOL Neutral
Denmark	MOVICOL Neutral
France	MOVICOL Sans Arôme
Finland	MOVICOL Plain
Ireland	MOVICOL Plain
Italy	MOVICOL 13,7 g polvere per soluzione orale, Senza Aroma
Luxembourg	MOVICOL Neutral
Netherlands	Movicolon Naturel
Spain	MOVICOL Sabor Neutro
Sweden	Movicol Neutral
United Kingdom (Northern Ireland)	MOVICOL Plain

This leaflet was last revised in 04/2023

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, please ring 00 44 1895 826 606.