

Patient Information Leaflet

MOVICOL® Plain

13.7 g sachet, powder for oral solution

Read all of this leaflet carefully before taking your medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is MOVICOL Plain 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. Before you take MOVICOL Plain

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

- a blockage of 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 or any of the other ingredients of MOVICOL Plain

Heart conditions

Follow the special instructions in section 3 if you are taking MOVICOL Plain for faecal impaction.

Pregnancy and breast feeding

MOVICOL Plain 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 Plain.

Taking other medicines

Some medicines, e.g. anti-epileptics, may not work as effectively during use with MOVICOL Plain.

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Driving and using machines

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

3. How to take MOVICOL Plain

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

Constipation

A dose of MOVICOL Plain is 1 sachet.

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 faecal impaction. 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, MOVICOL Plain can have side effects.

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.

If any of the above are troublesome or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store MOVICOL Plain

Keep all medicines out of the reach and sight of children

Do not use MOVICOL Plain after the expiry date on the sachet and carton.

Do not store above 25°C.

Once you have made up MOVICOL Plain 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 in a 6 hour period.

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.

6. Further Information

Each 13.7g 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
Hydrogen carbonate	17 millimoles/litre
Potassium	5.4 millimoles/litre

What MOVICOL Plain looks like and contents of the pack

MOVICOL Plain is a powder for oral solution. MOVICOL Plain is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets. Not all pack sizes may be marketed.

UK Marketing authorisation holder:

Norgine BV, Hoeglweg 7, 1101 CA Amsterdam ZO, The Netherlands.

IE Marketing authorisation holder:

Norgine Ltd, Moorhall Road, Harefield, Uxbridge, Middx, UB9 6NS UK

Manufacturer:

Norgine Ltd, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, U.K.

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

Austria	MOVICOL Aromafrei
Belgium	MOVICOL Neutral
Finland	MOVICOL Plain
Ireland	MOVICOL Plain
Italy	MOVICOL Dearoma
Netherlands	MOVICOLon Naturel
Spain	MOVICOL Sabor Neutro
Sweden	MOVICOL Neutral
Switzerland	MOVICOL Aromafrei
United Kingdom	MOVICOL Plain

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