



PACKAGE LEAFLET

Package Leaflet: Information for the patient

Movicol[®] Chocolate 13.9g, sachet powder for oral solution

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

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

The name of this product is Movicol Chocolate 13.9 g 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 Chocolate helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol Chocolate also works in very bad constipation known as faecal impaction.

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

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

Warnings and precautions

When taking Movicol Chocolate 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 Chocolate for faecal impaction.

Other medicines and Movicol Chocolate

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 Chocolate.

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

Pregnancy and breast feeding

Movicol Chocolate 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 Chocolate.

Driving and using machines

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

Movicol Chocolate contains benzyl alcohol

Movicol Chocolate contains 14.1 mg of benzyl alcohol per sachet. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease, are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Movicol Chocolate 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 Chocolate 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 Chocolate

This medicine can be taken 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 Chocolate 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 Chocolate for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Movicol Chocolate 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 125 ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol Chocolate solution is clear or slightly hazy, then drink it. If you are taking Movicol Chocolate for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment**Constipation:**

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

If you take more Movicol Chocolate than you should

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

If you forget to take Movicol Chocolate

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 Chocolate if you:

- Get a serious allergic reaction which causes difficulty in breathing or dizziness or swelling of the face, lips and 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 or 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 experience soreness of the anus (bottom) and you may have mild diarrhoea when starting to take Movicol Chocolate. These side effects generally get better if you reduce the amount of Movicol Chocolate 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 HPRa 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 Chocolate

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

Do not use Movicol Chocolate after the expiry date which is stated on the sachet and carton.

This medicinal product does not require any special storage conditions.

Once you have made up Movicol Chocolate 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 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 Chocolate contains

Each 13.9g sachet of Movicol Chocolate contains the following:

| | |
|---------------------------|---------|
| Macrogol 3350 | 13.125g |
| Sodium Chloride | 0.3507g |
| Sodium Hydrogen Carbonate | 0.1785g |
| Potassium Chloride | 0.0317g |

Movicol Chocolate also contains chocolate flavour, and acesulfame potassium E950 as a sweetener. Chocolate flavour contains the following ingredients maltodextrin (potato), gum arabic/acacia gum E414, vegetable oils and fats (coconut), propylene glycol E1520 and benzyl alcohol E1519 (see section 2 “Movicol Chocolate contains benzyl alcohol”).



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

| | |
|--------------------|----------------------|
| Sodium | 65 millimoles/litre |
| Chloride | 51 millimoles/litre |
| Potassium | 5.4 millimoles/litre |
| Hydrogen Carbonate | 17 millimoles/litre |

What Movicol Chocolate looks like and the contents of the pack

Movicol Chocolate is a white to light brown powder.

Movicol Chocolate is available in boxes of 20 or 30 sachets.

Marketing Authorisation Holder

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

Manufacturer:

Norgine Limited, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, UK.

Or

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

Or

Recipharm Höganäs AB, Sporthallsvägen 6, Höganäs, 263 35, Sweden.

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

| | |
|-------------|---|
| Belgium | MOVICOL Chocoladesmaak/MOVICOL Goût chocolat/MOVICOL Schokoladengeschmack |
| Denmark | MOVICOL Chokolade |
| Finland | MOVICOL Chocolate |
| France | MOVICOL Chocolat |
| Ireland | MOVICOL Chocolate |
| Luxembourg | MOVICOL Goût Chocolat |
| Netherlands | MOVICOLON Chocolate |
| Norway | MOVICOL med sjokoladesmak |
| Sweden | Movicol Choklad |
| UK | MOVICOL Chocolate |

This leaflet was last revised in: 11/2021

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.