

Patient Information Leaflet

MOVICOL® CHOCOLATE

13.9g sachet, powder for oral solution

Read all of this leaflet carefully before taking your medicine.

This medicine is available without prescription.

However, you still need to take MOVICOL Chocolate carefully to get the best results from it.

-Keep this leaflet. You may need to read it again.

-Ask your pharmacist if you need more information or advice.

-You must contact a doctor if your symptoms worsen or do not improve.

-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.

If you need the information on this leaflet to be supplied in an alternative format, such as large print, please ring from the UK: 0800 198 5000.

In this leaflet:

1. What is MOVICOL Chocolate and what is it used for?

2. Before you take MOVICOL Chocolate

3. How to take MOVICOL Chocolate

4. Possible side effects

5. How to store MOVICOL Chocolate

6. Further information.

1. What is MOVICOL Chocolate and what is it used for?

The name of this medicine is MOVICOL Chocolate 13.9g 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 called faecal impaction.

2. 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 any of the ingredients

Take special care with MOVICOL Chocolate

Heart conditions

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

Taking other medicines

Some medicines e.g. anti-epileptics may not work as effectively during use with MOVICOL Chocolate. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines including medicines obtained without a prescription.

Taking MOVICOL Chocolate with food or drink

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

Pregnancy and breast feeding

MOVICOL Chocolate 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 Chocolate.

Driving and using machines

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

3. How to take MOVICOL Chocolate

Constipation:

A dose of MOVICOL Chocolate is 1 sachet.

Take this 1–3 times a day according to the severity of your constipation.

Faecal impaction:

A dose of 8 sachets a day of MOVICOL Chocolate is needed for the treatment of 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 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 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.

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, MOVICOL Chocolate can have side effects.

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.

If any of the above become serious 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 Chocolate

Keep out of the reach and sight of children.

Do not use MOVICOL Chocolate after the expiry date shown on the sachet.

Do not store sachet above 25°C.

Once you have made up MOVICOL Chocolate 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 within 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 13.9g sachet of MOVICOL Chocolate contains the following:

Macrogol 3350 13.125 g

Sodium Chloride 0.3507 g

Sodium Hydrogen Carbonate 0.1785 g

Potassium Chloride 0

0.0317 g

MOVICOL Chocolate also contains chocolate flavour, and acesulfame potassium as a sweetener.

Chocolate flavour contains the following ingredients:

maltodextrin (potato); gum arabic/acacia gum E414, vegetable oils and fats (palm/coconut oil), propylene glycol E1520 and ethyl 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 Ltd., Moorhall Road, Harefield, Middlesex, UB9 6NS, UK.

Manufacturer:

Norgine Ltd, New Road, Hengoed,

Mid Glamorgan, CF82 8SJ, U.K.

MOVICOL Chocolate is available in Europe. In Ireland and Finland it is known as MOVICOL Chocolate, in Austria MOVICOL schoko, in Belgium MOVICOL Chocoladesmaak/MOVICOL Gout chocolat/MOVICOL Schokoladengeschmack and in Sweden MOVICOL Choklad.