Package Leaflet: Information for the User.

MOVIPREP®

Powder for oral solution

For a list of active substances please see section 6.

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may be harmful even if their symptoms are the same as yours.
- If any of the side effects gets 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 in an alternative format, such as large text, please ring Medical Information, From the UK: 01895 826 606. From Ireland: 00 44 1895 826 606.

In this leaflet:

1. WHAT MOVIPREP IS AND WHAT IS IT USED FOR

MOVIPREP is a lemon flavoured laxative contained in four sachets. There are two large sachets ('Sachet A') and two small sachets ('Sachet B'). You need all these for one treatment.

You are taking MOVIPREP to make your bowels clean so that they are ready for examination.

MOVIPREP works by emptying the contents of your bowels, so you should expect to have watery bowel movements.

2. BEFORE YOU TAKE MOVIPREP

Do not take MOVIPREP if you suspect or your doctor suspects:
- you are allergic (hypersensitive) to macrogol 3350 or any of the other ingredients of MOVIPREP.
- you have an obstruction in your intestine (gut).
- you have a perforated gut wall.
- you have a disorder of stomach emptying.
- you have paralysis of the gut (often occurs after an operation to the abdomen).
- you suffer from phenylketonuria. This is an hereditary inability of the body to use a particular amino acid. MOVIPREP contains a source of phenylalanine.
- your body is unable to produce enough glucose-6-phosphate dehydrogenase.
- you have toxic megacolon (a severe complication of acute colitis).

Take special care with MOVIPREP

If you are in poor health or have a serious medical condition, you should be particularly aware of the possible side effects listed in section 4. Contact your doctor or pharmacist if you are concerned. You should tell your doctor before taking MOVIPREP if you have any of the following:
- you need to thicken fluids in order to swallow them safely.
- a tendency to regurgitate swallowed drink, food or acid from the stomach.
- kidney disease.
- heart failure.
- dehydration.
- acute flare of inflammatory bowel disease (Crohn's disease or ulcerative colitis).

MOVIPREP should not be given to patients with impaired consciousness without medical supervision.

Taking other medicines

If you are taking other medicines take them at least one hour before taking MOVIPREP or at least one hour afterwards because they may be flushed through your digestive system and not work so well.

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

Taking MOVIPREP with food and drink

Do not take any solid food from when you start to take MOVIPREP until after the examination.

Pregnancy and breast-feeding

There are no data on the use of MOVIPREP during pregnancy or lactation and it should only be used if considered essential by the physician. So if you are pregnant or breast feeding talk to your doctor before taking MOVIPREP.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

MOVIPREP does not affect your ability to drive or use machines.

Important information about some of the ingredients of MOVIPREP

This medicinal product contains 56.2 mmol of absorbable sodium per litre. To be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains 14.2 mmol of potassium per litre. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Contains a source of phenylalanine. May be harmful for people with phenylketonuria.

3. HOW TO TAKE MOVIPREP

Always take MOVIPREP exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 2 litres of solution, which is made up as follows:

This pack contains 2 clear bags each containing one pair of sachets: Sachet A and Sachet B.

Each pair of sachets (A and B) is to be dissolved in one litre of water This pack is therefore sufficient to make up 2 litres of MOVIPREP solution.

Before you take MOVIPREP, please read carefully the following instructions. You need to know:
- When to take MOVIPREP
- How to prepare MOVIPREP solution
- How to drink MOVIPREP
- What you should expect to happen

When to take MOVIPREP

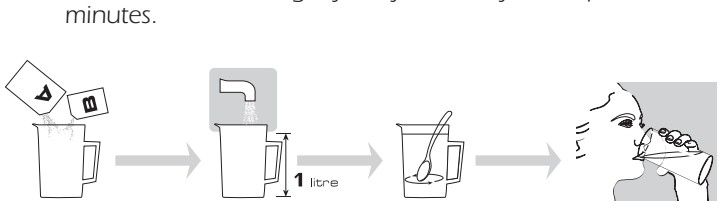
You should have been given instructions about when to take MOVIPREP by your doctor or nurse. Your treatment with MOVIPREP must be completed before your clinical examination and can be taken:

either divided as 1 litre of MOVIPREP in the evening and 1 litre in the early morning of the day of the examination,

or 2 litres in the evening before the examination.

Important: Do not take any solid food from when you start to take MOVIPREP until after the examination.

How to prepare MOVIPREP
- Open one clear bag and remove the sachets A and B
- Add the contents of BOTH sachet A and sachet B to a measuring jug that holds 1 litre.
- Add water into the container up to the 1 litre mark and stir until all the powder has dissolved and the MOVIPREP solution is clear or slightly hazy. This may take up to 5 minutes.



How to drink MOVIPREP

Drink the first litre of the MOVIPREP solution over one to two hours. Try to drink a glassful every 10-15 minutes.

When you are ready, make up and drink the second litre of MOVIPREP solution made up with the contents of the sachets A and B from the remaining bag.

During the course of this treatment, you are recommended to drink a further one litre of clear liquid to prevent you feeling very thirsty and becoming dehydrated. Water, clear soup, fruit juice (without pulp), soft drinks, tea or coffee (without milk) are all suitable. These drinks can be taken at any time you choose.

What you should expect to happen

When you start drinking the MOVIPREP solution, it is important that you stay close to a toilet.

At some point, you will start to experience watery bowel movements. This is quite normal and indicates that the MOVIPREP solution is working.

The bowel movements will stop soon after you have finished drinking.

If you follow these instructions, your bowel will be clear, and this will help you to have a successful examination.

If you take more MOVIPREP than you should

If you take more MOVIPREP than you should you may develop excessive diarrhoea, which can lead to dehydration. Take generous amounts of fluid, especially fruit juices. If you are worried contact your doctor or pharmacist.

If you forget to take MOVIPREP

If you forget to take MOVIPREP take the dose as soon as you realize you have not taken it.

If this is several hours after the time when you should have taken it, contact your doctor or pharmacist for advice. It is important that you complete your preparation at least an hour before your procedure.

If you have any further questions on the use of this product, ask you doctor or pharmacist.

Children

MOVIPREP should not be taken by children aged below 18 years.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MOVIPREP can have side effects although not everybody gets them.

It is normal to get diarrhoea when you take MOVIPREP.

Very common side effects (i.e. affects more than 1 user in 10) are:

Abdominal pain, abdominal distension, tiredness, feeling generally unwell, soreness of the anus, and nausea.

Common side effects (i.e. affects 1 to 10 users in 100) are: Hunger, problems sleeping, dizziness, headache, vomiting, indigestion, thirst and chills.

Uncommon side effects (i.e. affects 1 to 10 users in 1000) are: discomfort, difficulties swallowing, and changes to tests of liver function.

The following side effects have sometimes been seen but it is not known how often they occur because the frequency cannot be estimated from the available data: flatulence (wind), temporary increase in blood pressure, retching (straining to vomit), very low blood sodium levels that can cause convulsions (fits) and changes to the levels of salts in the blood such as decreased bicarbonate, increased or decreased calcium, increased or decreased chloride and decreased phosphate. Blood potassium and sodium levels could also decrease particularly in patients taking medicines that affect the kidney such as ACE inhibitors and diuretics used for the treatment of heart disease.

These reactions usually only occur for the duration of the treatment. Should they persist, consult your doctor.

Allergic reactions may occur.

If you experience any of the following, stop your intake of MOVIPREP and contact your doctor immediately. You should not take any more MOVIPREP until you have checked with your doctor.

- rash or itching
- swelling of your face, ankles or other part if your body
- palpitations
- extreme fatigue
- shortness of breath

If you do not have a bowel movement within 6 hours of taking MOVIPREP, stop the intake and contact your doctor immediately.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. STORING MOVIPREP

Keep out of the reach and sight of children.

Do not use MOVIPREP after the expiry date which is stated on the carton and sachets.

The expiry date refers to the last day of the month.

Keep MOVIPREP sachets at room temperature (not above 25°C).

After you have dissolved MOVIPREP in the water, the solution may be stored (keeping covered) at room temperature (not above 25°C). It may also be stored in the fridge (2°C - 8°C). Do not keep it for more than 24 hours.

40601204

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

Sachet A contains these active substances:

Macrogol (also known as polyethylene glycol) 3350	100 g
Sodium sulphate anhydrous	7.500 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B contains these active substances:

Ascorbic acid	4.700 g
Sodium ascorbate	5.900 g

The concentration of electrolyte ions when both sachets are made up to one litre of solution is as follows:

Sodium (of which not more than 56.2 mmol is absorbable)	181.6 mmol/l
Chloride	59.8 mmol/l
Sulphate	52.8 mmol/l
Potassium	14.2 mmol/l
Ascorbate	29.8 mmol/l

Other ingredients are:

Lemon flavouring (containing maltodextrin, citral, lemon oil, lime oil, xanthan gum, vitamin E), aspartame (E951) and acesulfame potassium (E950) as sweeteners.

What MOVIPREP looks like and contents of the pack

This pack contains 2 clear bags each containing one pair of sachets: Sachet A and Sachet B. Each pair of sachets (A and B) is to be dissolved in one litre of water.

MOVIPREP powder for oral solution in sachets is available in pack sizes of 1, 10, 40, 80, 160 and 320 packs of a single treatment. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Norgine BV, Hogehilweg 7, 1101CA Amsterdam ZO, The Netherlands

Manufacturer:

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

NORGINE

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

Country

Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and United Kingdom: MOVIPREP

Sweden: MOVPREP

This leaflet was last approved in 07/2011

The following information is intended for medical or healthcare professionals only.

Note for medical staff:

MOVIPREP should be administered with caution to fragile patients in poor health or patients with serious clinical impairment such as:

- impaired gag reflex, or with a tendency to aspiration or regurgitation
- impaired consciousness
- severe renal insufficiency (creatinine clearance <30 ml/min)
- cardiac impairment (NYHA grade III or IV)
- dehydration
- severe acute inflammatory disease

The presence of dehydration should be corrected before the use of MOVIPREP.

Semi-conscious patients or patients prone to aspiration or regurgitation should be closely observed during administration especially if this is via a nasogastric route.

MOVIPREP should not be given to unconscious patients.