

Patient Package Insert according to Pharmacists' Regulations

(Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Moviprep

Powder for oral solution

Active ingredients and their quantity:

Sachet 1 contains:	
Macrogol (also known as polyethylene glycol) 3350	100 grams
Sodium sulfate anhydrous	7.5 grams
Sodium chloride	2.691 grams
Potassium chloride	1.015 grams

Sachet 2 contains:	
Ascorbic acid	4.7 grams
Sodium ascorbate	5.9 grams

The concentration of electrolyte ions after dissolving the two sachets in water to prepare one litre of solution is:

Sodium	181.6 millimole/litre (of which no more than 56.2 millimoles is absorbable).
Chloride	59.8 millimole/litre
Sulfate	52.8 millimole/litre
Potassium	14.2 millimole/litre
Ascorbate	56.5 millimole/litre

Inactive ingredients and allergens in the medicine: see section 6 "Additional information".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It might harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

Moviprep is intended to clean the bowels before any clinical procedure that requires emptying the bowel before performing it, such as an endoscopy of the bowel or radiology in the bowel area.

What is Moviprep?

Moviprep is a lemon flavored laxative packaged in four sachets. There are two large sachets ("sachet 1") and two small sachets ("sachet 2"). All of these sachets are needed for one treatment.

Moviprep is intended for treatment to clean the bowels so they will be ready for examination.

Moviprep acts by emptying the contents of your bowels, therefore you should expect to have watery bowel movements.

Therapeutic group: osmotic laxative.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredients or to any of the other ingredients this medicine contains (listed in section 6).
- 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 a hereditary disease that damages the ability of the body to use a particular amino acid. Moviprep contains a source of phenylalanine.
- your body is unable to produce a sufficient amount of the G6PD enzyme (glucose-6-phosphate dehydrogenase).
- you have toxic megacolon (a severe complication of acute colitis).

Special warnings regarding the use of this medicine

If you are in poor health or have a serious medical problem, you should be particularly aware of the possible side effects listed in section 4. Consult your doctor or pharmacist if you are concerned.

Before treatment with the medicine, tell the doctor if you suffer from any of the following conditions:

- You tend to regurgitate fluids, food or acid from the stomach after swallowing them.
- Kidney disease
- Heart failure or heart disease, including high blood pressure, irregular heartbeats or palpitations
- Thyroid disease
- 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.

If you experience sudden abdominal pain or rectal bleeding when taking Moviprep for bowel preparation, contact the doctor or seek medical advice immediately.

Children and adolescents

The medicine is not intended for children and adolescents aged below 18 years.

Drug interactions:

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist.

If you need to thicken fluids in order to swallow them safely, the Moviprep preparation may neutralize the influence of the thickening substance.

If you are taking other medicines orally (such as: birth control pills), do not take them one hour before using Moviprep, one hour after using Moviprep, or while taking Moviprep, because the medicines may be flushed through your digestive system at this time and not work properly.

Use of this medicine and food

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

When taking Moviprep you should continue to take plenty of fluids. The fluid content of Moviprep does not replace your regular fluid intake.

Pregnancy, breast-feeding and fertility

There are no data on the use of Moviprep during pregnancy or breast-feeding and the medicine should only be used if considered essential by the doctor.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using the medicine.

Driving and use of machinery

Moviprep does not affect your ability to drive or operate machinery.

Important information about some of the ingredients of this medicine

Moviprep contains sodium, potassium and a source of phenylalanine
This medicine contains 8.4 grams of sodium (main component of cooking/table salt) per course of treatment. (A course of treatment consists of 2 litres of Moviprep). This amount is equivalent to 420% of the maximum recommended daily dietary intake of sodium for an adult. Patients on a controlled sodium diet should take this into consideration. Only a proportion (up to 2.6 grams per course of treatment) of sodium is absorbed.

This medicine contains 1.1 grams of potassium per course of treatment. (A course of treatment consists of 2 litres of Moviprep). Patients with reduced kidney function or patients on a controlled potassium diet should take this into consideration.

The medicine contains a source of phenylalanine. It may be harmful to people with phenylketonuria.

3. How to use this medicine

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen. The dosage and treatment regimen will be determined by the doctor only. The usual recommended dosage is two litres of solution, prepared as follows:

This package contains two clear bags, each containing one pair of sachets: sachet 1 and sachet 2. Dissolve each pair of sachets (1 and 2) in water to prepare one litre of solution. This package is therefore sufficient to prepare two litres of Moviprep solution.

Do not exceed the recommended dose.

Before you take Moviprep, please carefully read the following instructions. You need to know:

- when to take Moviprep
- how to prepare Moviprep
- how to drink Moviprep
- what should be expected to happen

When to take it?

Always be sure to take this medicine exactly as explained in this leaflet or as the doctor has told you. Ask your doctor if you are not sure. The treatment with Moviprep must be completed before your examination:

The treatment can be taken either as divided into two doses or as a single dose according to the way the examination is carried out (with or without general anaesthesia), as described below:

When the examination is conducted under general anaesthesia:

1. **Divided into two doses:** Drink one litre of Moviprep in the evening before the examination and one litre of Moviprep early in the morning of the day on which the examination is conducted.

It is important to finish drinking the entire amount of Moviprep (2 litres) and other clear fluids (see details of the fluids under "Important") at least two hours before the start of the examination.

2. **Single dose:** Drink two litres of Moviprep in the evening before the examination or two litres of Moviprep in the morning of the day on which the examination is conducted.

It is important to finish drinking the entire amount of Moviprep (2 litres) and other clear fluids (see details of the fluids under "Important") at least two hours before the start of the examination.

When the examination is conducted without general anaesthesia:

1. **Divided into two doses:** Drink one litre of Moviprep in the evening before the examination and one litre of Moviprep early in the morning of the day on which the examination is conducted.

It is important to finish drinking the entire amount of Moviprep (2 litres) and other clear fluids (see details of the fluids under "Important") at least one hour before the start of the examination.

2. **Single dose:** Drink two litres of Moviprep in the evening before the examination or two litres of Moviprep in the morning of the day on which the examination is conducted.

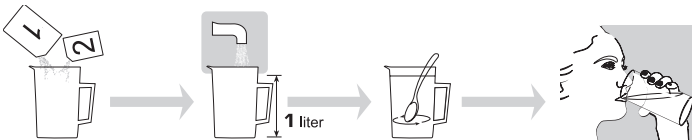
It is important to finish drinking the entire amount of Moviprep (2 litres) at least two hours before the start of the examination. Finish drinking other clear fluids (see details of the fluids under "Important") at least one hour before the start of the examination.

Important: Do not take any solid food from the moment you begin to drink Moviprep until after the examination.

While drinking Moviprep it is recommended to drink an additional litre of clear fluid to prevent you feeling very thirsty and becoming dehydrated. Appropriate drinks are: water, clear soup, fruit juice (without pulp), soft drinks, tea or coffee (without milk). You can take these drinks up to two hours before the examination at the latest if the examination is conducted under general anaesthesia, or up to an hour before the examination at the latest if the examination is conducted without general anaesthesia.

How to prepare Moviprep

- Open one clear bag and remove the sachets 1 and 2.
- Add the contents of BOTH sachets – sachet 1 and sachet 2 – to a measuring jug that holds one litre.
- Add water up to the one litre mark of the container and stir until all the powder has dissolved and the Moviprep solution is clear or slightly hazy. This may take up to five minutes.



How to drink Moviprep

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

When you are ready, make up and drink the second litre of Moviprep solution that you will prepare with the contents of sachets 1 and 2 from the remaining bag.

What should be expected to happen

When you begin to drink Moviprep solution, it is important to stay close to a toilet. At a certain point, you will begin to have watery bowel movements. This is expected, and it shows that Moviprep solution is working. The bowel movements will stop soon after you finish drinking the solution.

If you follow these instructions, bowel will be clear, and this will help to have a successful examination. After drinking the last dose you must leave enough time to travel to the place where the colonoscopy will be performed.

If you have accidentally taken too much Moviprep, you may develop serious diarrhea, which may cause dehydration. Drink large amounts of fluids, especially fruit juices. If you are concerned, call your doctor or the pharmacist.

If you have taken an overdose or if a child or someone else has accidentally swallowed some medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the set time, drink the dose as soon as you realize you did not drink it. If this happens several hours after you were supposed to drink it, refer to your doctor or the pharmacist and consult them. **It is important to complete your preparation on time, according to the time details appearing at the start of the section (section 3 – "How to use this medicine", under the heading "When to take it?").**

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the use of Moviprep may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

It is normal to get diarrhea when you take Moviprep.

Stop the use of this medicine and refer to a doctor immediately if you have any of the following side effects:

- Rash or itching
- Swelling of the face, ankles, or other parts of the body
- Palpitations
- Extreme fatigue
- Shortness of breath

These are symptoms of a severe allergic reaction.

If you do not have bowel movements within 6 hours after drinking Moviprep, stop drinking and refer to the doctor immediately.

Additional side effects include:

Very common side effects - effects that appear in more than one user of 10:

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

Common side effects - effects that appear in up to one user out of 10:

Hunger, problems sleeping, dizziness, headache, vomiting, indigestion, thirst, chills.

Uncommon side effects - effects that appear in up to one user out of 100:

Discomfort, difficulties swallowing, changes in liver function test results.

Side effects with unknown frequency (effects for which a frequency has not been determined yet):

Flatulence in the abdomen (wind, intestinal gas), a temporary increase in blood pressure, irregular heart rhythm or palpitations, dehydration, retching (straining to vomit), very low blood sodium levels which may cause convulsions (fits) and changes to the levels of salts in the blood such as decreased bicarbonate level, increased or decreased calcium level; increased or decreased chloride levels and decreased phosphate levels. The potassium and sodium levels in the blood may also decrease. These reactions usually only occur for the duration of the treatment. Should they persist, consult your doctor.

Allergic reactions may cause a skin rash, itching, reddening of the skin or a nettle rash (urticaria), swollen hands, feet or ankles, headaches, palpitations and shortness of breath.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via the following address: Padagis.co.il

5. How to Store the Medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package.
- Please note that the expiry dates may be different for the different sachets.
- The expiry date refers to the last day of that month.
- Store the Moviprep sachets below 25°C.
- After dissolving Moviprep in water, the solution can be stored (in a closed container) at room temperature (below 25°C). It can also be stored in the refrigerator (2°C - 8°C). Do not keep it for more than 24 hours.
- Use the bag immediately after opening it.
- Do not dispose of the medicine via wastewater or household waste. Ask your pharmacist how to dispose of the medicine. This will help to protect the environment.

6. Additional Information

In addition to the active ingredients, the medicine also contains:

Lemon flavouring, aspartame, acesulfame potassium as sweeteners.

For additional information see section 2.

What the medicine looks like and contents of the package:

The package contains two clear bags, each containing a pair of sachets: sachet 1 and sachet 2.

Dissolve each pair of sachets (1 and 2) in one litre of water.

Moviprep powder in sachets for oral solution is marketed in packages of one pack.

Registration Holder: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Manufacturer: Norgine Limited., Middlesex, England.

Revised in May 2023 according to Ministry of Health guidelines.

Drug registration number at the national medicines registry of the Ministry of Health:
145 38 33156

21.02.2023

Moviprep PIL PB0623-01