**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE 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 3350 | 100 gram |
| Sodium sulfate anhydrous | 7.5 gram |
| Sodium chloride | 2.691 gram |
| Potassium chloride | 1.015 gram |
| Sachet 2 contains: | |
| Ascorbic acid | 4.7 gram |
| Sodium ascorbate | 5.9 gram |

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

| | |
|---|---|
| Sodium | 181.6 millimole/liter (of which no more than 56.2 millimoles are absorbable) |
| Chloride | 59.8 millimole/liter |
| Sulfate | 52.8 millimole/liter |
| Potassium | 14.2 millimole/liter |
| Ascorbate | 56.5 millimole/liter |

**Inactive ingredients and allergens in the preparation: see in section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information".**

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. 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 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 additional ingredients contained in the medicine (listed in section 6 “Additional information”).
- you have an intestinal (gut) obstruction.
- you have a perforated gut wall.
- you have a stomach emptying disorder.
- you have paralysis of the gut (often occurs after an operation to the abdomen).
- you suffer from phenylketonuria, a hereditary inability of the body to use particular amino acids. 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 a severe complication of acute colitis (toxic megacolon).

**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 “Side effects”. Refer to your doctor or pharmacist if you are concerned.

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

- A tendency to regurgitate drinks or food after swallowing them or acid from the stomach, or if you have swallowing problems (also see section “Use of this medicine and food”).
- Kidney disease.
- Heart failure, severe kidney problems or if you are taking a blood pressure medicine.
- 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).
- Epilepsy or history of convulsions.

**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.**

If you experience vomiting (blood), followed by sudden chest, neck or abdominal pain, difficulty swallowing or breathing when taking Moviprep, stop taking the medicine and refer to your doctor 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 nutritional supplements, tell the doctor or pharmacist.**

If you are taking other medicines orally (such as: birth control pills), do not take them one hour before using Moviprep, while taking Moviprep or one hour after using Moviprep because the medicines may be flushed through your digestive system and not work properly. If you are taking oral contraceptives, you may have to use additional contraceptives (e.g., a condom) to prevent pregnancy.

**Use of this medicine and food**
Do not take any solid foods from when you start to take Moviprep until after the examination.
If you need to thicken fluids in order to swallow them safely, Moviprep may neutralize the influence of the thickening substance.
When taking Moviprep you should continue to take in plenty of fluids. The fluid content of Moviprep does not replace your regular fluid intake.

**Pregnancy, breastfeeding and fertility**
There are no data on the use of Moviprep during pregnancy or breastfeeding and the medicine should only be used if considered essential by your doctor.
If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this 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 gram of sodium (main component of cooking/table salt) per course of treatment (a course of treatment consists of 2 liters 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 part (up to 2.6 grams per treatment dose) of the sodium is absorbed.
This medicine contains 1.1 gram of potassium per treatment dose (a treatment dose consists of 2 liters of Moviprep). Patients with reduced kidney function or patients on a controlled-potassium diet should take this into consideration.
This medicine contains 0.233 gram aspartame in each sachet 1. Aspartame is a source of phenylalanine that may harm you if you have phenylketonuria, which is a rare hereditary disorder in which phenylalanine accumulates because the body is unable to remove it properly.

## 3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparations. The dosage and treatment regimen will be determined by the doctor only. The usual recommended dosage is two liters 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 liter of solution. Therefore, this package is sufficient to prepare two liters 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 divided into two doses or all in a single dose, as described below:

**When the examination is conducted under general anesthesia:**
1. Divided into two doses: Drink one liter of Moviprep in the evening before the examination and one liter of Moviprep early in the morning of the day on which the examination is conducted.
   Be sure to finish drinking the entire amount of Moviprep (2 liters) 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 liters of Moviprep in the evening before the examination or two liters of Moviprep in the morning of the day on which the examination is conducted.
   Be sure to finish drinking the entire amount of Moviprep (2 liters) and other clear fluids (see details of the fluids under "Important") at least two hours before the start of the examination.

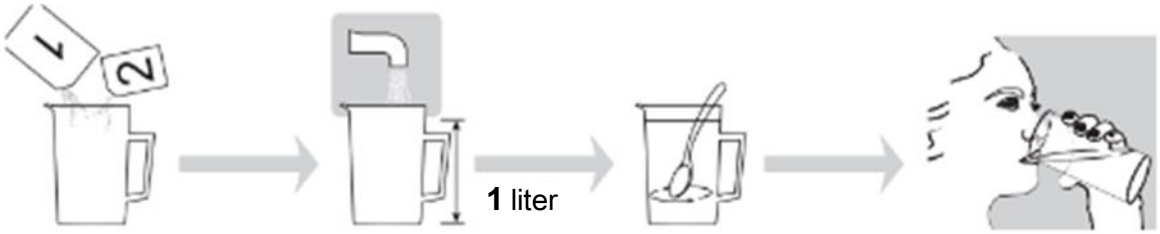
**When the examination is conducted without general anesthesia:**
1. Divided into two doses: Drink one liter of Moviprep in the evening before the examination and one liter of Moviprep early in the morning of the day on which the examination is conducted.
   Be sure to finish drinking the entire amount of Moviprep (2 liters) 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 liters of Moviprep in the evening before the examination or two liters of Moviprep in the morning of the day on which the examination is conducted.
   Be sure to finish drinking the entire amount of Moviprep (2 liters) at least two hours before the start of the examination. Be sure to 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 eat solid food from the moment you begin to drink Moviprep until after the examination.**
**During treatment with Moviprep, it is recommended that you drink an additional liter of *clear* fluid so that you will not feel very thirsty and become 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 an examination conducted under general anesthesia, and up to one hour before an examination conducted without general anesthesia.**

**How to prepare Moviprep**

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




**How to drink Moviprep**

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

When you are ready, prepare and drink the second liter 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 shows that Moviprep solution is working. The bowel movements will stop soon after you finish drinking the solution.

If you follow these instructions, the bowel will be empty, and this will help you 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 a higher dosage of 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 has accidentally swallowed the 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, take the dose as soon as you realize that you did not take it. If this happens several hours after you were supposed to take 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 should you use the 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 use 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.

Stop taking Moviprep and refer to a doctor immediately if you notice any of the following side effects:

- Seizure

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

**Additional side effects include:**
Very common side effects – effects that appear in more than one user in ten:
Abdominal pain, abdominal distension, tiredness, generally feeling unwell, soreness of the anus, nausea, fever.

Common side effects – effects that appear in 1-10 in 100 users:
Hunger, problems sleeping, dizziness, headache, vomiting, indigestion, thirst, chills.

Uncommon side effects – effects that appear in 1-10 in 1,000 users:
Discomfort, difficulties swallowing, changes in liver function test results.

Side effects of unknown frequency (effects whose frequency has not been determined yet):
Flatulence (wind), a temporary increase in blood pressure, irregular heart rhythm or palpitations, dehydration, retching, esophageal rupture due to vomiting, very low blood sodium levels which may cause convulsions (fits) and changes in 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 urticaria, swollen hands, feet or ankles, headaches, palpitations and shortness of breath.

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

Reporting 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 for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il
Additionally, they can be reported to Padagis via the following address: padagis.co.il

## 5. HOW SHOULD THE MEDICINE BE STORED?

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.
**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.
Shelf life after preparation: After dissolving the two sachets in 1 liter water to prepare the oral solution, the resulting solution can be stored in a closed container, for up to 24 hours at a temperature below 25 °C or in a refrigerator (2°C-8°C).
Use the sachets immediately after opening them.
Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

## 6. ADDITIONAL INFORMATION

**In addition to the active ingredients, the medicine also contains:**
Sachet 1:
Lemon flavor, Aspartame, Acesulfame potassium.
For further information, see section 2 "Important information about some of the ingredients in this medicine".

**What the medicine looks like and contents of the package:**
This 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 liter 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 March 2025.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 145 38 33156



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