

## **Moviprep**

Powder for solution for oral use

### **Active ingredients:**

Sachet number 1 contains:

Macrogol 3350	100 g
Sodium Sulfate anhydrous	7.5 g
Sodium Chloride	2.691 g
Potassium Chloride	1.015 g

Sachet number 2 contains:

Ascorbic Acid	4.7 g
Sodium Ascorbate	5.9 g

The concentration of electrolytes after dissolving Sachet 1 and Sachet 2 in water to prepare one liter of solution is as follows:

Sodium	181.6 mmol/l (among them not more than 56.2 mmol are absorbable)
Sulphate	52.8 mmol/l
Chloride	59.8 mmol/l
Potassium	14.2 mmol/l
Ascorbate	29.8 mmol/l

Inactive ingredients and allergens: See section 6 "Additional information".

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

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

The medicine should not be taken by children aged below 18 years.

### **1. What is this medicine intended for?**

Moviprep is intended for clearing the bowels before any clinical procedure in the region of the bowel that requires it's emptying before performing the procedure, e.g., endoscopy of the bowel or radiology in the bowel region.

### **What is Moviprep?**

Moviprep is a lemon flavored laxative contained in four sachets. There are two large sachets ('sachet 1') and two small sachets ('sachet 2'). You need all these for one treatment.

Moviprep is intended for adult patients to clean the bowel 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.

**Therapeutic group:** Osmotically acting laxative.

### **2. Before using this medicine**

#### **X Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients of this medicine (listed in section 6).
- You have 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 inability of the body to use a particular amino acid. Moviprep contains a source of phenylalanine.
- Your body is unable to produce enough of the enzyme G6PD (glucose-6-phosphate

dehydrogenase).

- You have toxic megacolon (a severe complication of acute colitis).

### **I Special warnings regarding the use of this medicine**

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 physician or pharmacist if you are concerned.

**Before using this medicine, tell your physician 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 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 poor 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.

**If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist.**

### **Using the medicine and food**

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

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

### **Pregnancy, breastfeeding and fertility**

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. If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant, you should consult a physician before taking this medicine.

### **Driving and using machines**

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

### **Important information about some of the medicine's ingredients**

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

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

This medicinal product contains a source of phenylalanine. May be harmful for people with phenylketonuria.

## **3. How should you use the medicine?**

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician. The recommended dose is:

**Two liters of solution, which is made up as follows:**

This pack contains two clear bags each containing one pair of sachets: sachet 1 and sachet 2. Each pair of sachets (1 and 2) is to be dissolved in water to make a one-liter solution. This pack is therefore sufficient to make up two liters of Moviprep solution.

**Do not exceed the recommended dose.**

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

- When to take Moviprep
- How to prepare Moviprep
- How to drink Moviprep
- What you should expect to happen

### When to take?

Always take this medicine exactly as described in this leaflet or as your physician has told you. Check with your physician if you are not sure. Your treatment with Moviprep must be completed before your clinical procedure.

This course of treatment can be taken either as divided or single doses as described below:

1. Divided doses: one liter of Moviprep in the evening before the clinical procedure and one liter of Moviprep in the early morning of the day of the clinical procedure.
2. Single dose: two liters in the evening before the clinical procedure **or two liters in the morning of the clinical procedure.**

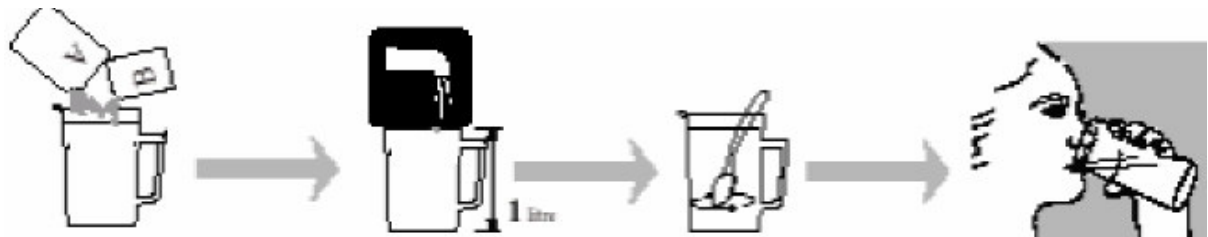
**For the divided dose and single dose taken in the evening before the clinical procedure there should be at least one hour between the end of intake of fluid (Moviprep or clear liquid) and the start of the colonoscopy.**

**For the single dose in the morning of the clinical procedure, there should be at least two hours between the end of intake of Moviprep and at least one hour between the end of intake of any clear liquid and the start of the colonoscopy.**

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

### How to prepare Moviprep

- Open one clear bag and remove the sachets 1 and 2.
- Add the contents of BOTH sachet 1 and sachet 2 to a measuring jug that holds 1 liter.
- Add water to make 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 hazy. This may take up to 5 minutes.



### How to drink Moviprep

Drink the first liter of 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 liter of Moviprep solution made up with the contents of the sachets 1 and 2 from the remaining bag.

During the course of this treatment, you are recommended to drink a further one liter of *clear* liquid to prevent you from 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. You should allow sufficient time after your last drink to travel to the colonoscopy unit.

**If you have taken a higher dose** you may develop excessive diarrhea, which can lead to dehydration. Take generous amounts of fluid, especially fruit juices. If you are worried contact your physician or pharmacist.

If a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine** at the scheduled time, 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 physician or pharmacist for advice. It is important that you complete your preparation at least an hour before your procedure when taking Moviprep as a divided dose and two hours before your procedure if taking all your Moviprep on the morning of the procedure.

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

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

#### **4. Side effects**

As with any medicine, Moviprep may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

It is normal to get diarrhea when you take Moviprep

#### **Stop treatment and refer immediately to the physician if you experience any of the following**

- Severe allergic reactions:
  - rash or itching
  - swelling of the face, ankles or other parts of your body
  - palpitations
  - extreme fatigue
  - shortness of breath
- If you do not have a bowel movement within 6 hours of taking Moviprep.

#### **Additional side effects**

##### Very common side effects – affects more than one user out of ten

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

##### Common side effects – affects 1-10 users out of 100

- Hunger
- sleeping problems
- dizziness
- Indigestion
- headache
- vomiting
- thirst
- chills

##### Uncommon side effects - affects 1-10 users out of 1,000

- discomfort
- difficulties swallowing
- changes of tests' results of liver function

##### Side effects of unknown frequency (frequency was not determined yet)

- flatulence
- temporary increase in blood pressure
- irregular heart rhythm or palpitations

- dehydration
- 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

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

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

If you experience any side effect, if any of the side effects gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

#### Reporting side effects

Side effects can be reported to the Ministry of Health directly via the MoH home page [www.health.gov.il](http://www.health.gov.il) or by the online form in the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton.
- 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 at a temperature below 25°C.
- After you have dissolved Moviprep in the water, the solution may be stored (keeping covered) at room temperature (below 25°C). It may also be stored in the fridge (2°C -8°C). Do not keep it for more than 24 hours.
- Do not discard the medicine to the wastewater or household waste. Consult the pharmacist about how to dispose of the medicine. These measures will help in environmental protection.

#### **6. Additional information**

##### **In addition to the active ingredients the medicine also contains:**

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

##### **What does the medicine look like and what are the contents of the package:**

This pack contains two clear bags each containing one pair of sachets: Sachet 1 and Sachet 2. Each pair of sachets (1 and 2) is to be dissolved in one liter of water.

Moviprep powder for oral solution in sachets is available in sizes of 1 pack.

**License holder:** Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei- Brak.

**Manufacturer:** Norgine limited, Norgine House, Widewater Place, Moorhall Rd., Harefield, Uxbridge, Middlesex, UB9 6NS, UK.

##### **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

145 38 33156

This leaflet was checked and approved by the Ministry of Health in: 29 of October 2015