

PART III: CONSUMER INFORMATION

MOVIPREP®

Macrogol (PEG) 3350, Sodium sulphate anhydrous, Sodium chloride, Potassium chloride, Ascorbic acid, Sodium ascorbate

This leaflet is part III of a three-part "Product Monograph" published when MOVIPREP was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MOVIPREP. Contact your doctor or pharmacist if you have any questions about the drug.

MOVIPREP can only be recommended by your doctor.

ABOUT THIS MEDICATION

What the medication is used for:

MOVIPREP helps empty the bowel (colon) as a preparation for colonoscopy in adults 18 years of age and older.

What it does:

All the ingredients in MOVIPREP act together to increase stool volume by attracting water to the stool, which stimulates the bowel to expel the contents in a laxative effect. The removal of bowel contents makes the clinical examination and visualization of the tissue easier.

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.

When it should not be used:

DO not take MOVIPREP if you suspect or your doctor suspects:

- You have serious conditions of the abdomen such as appendicitis or diverticulitis (fold within the intestinal wall which may be swollen and infected);
- You are allergic (hypersensitive) to Macrogol 3350 (Polyethylene glycol 3350) or any of the other ingredients of MOVIPREP (see what the non-medicinal ingredients are).
- 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 have toxic megacolon (a severe complication of acute colitis).

What the medicinal ingredient is:

Sachet A contains the following medicinal ingredients:

Macrogol (also known as polyethylene glycol) 3350
Sodium sulphate anhydrous
Sodium chloride
Potassium chloride

Sachet B contains the following medicinal ingredients:

Ascorbic acid
Sodium ascorbate

What the important nonmedicinal ingredients are:

MOVIPREP powder for oral solution, contains the following nonmedicinal ingredients: acesulfame potassium (E950) and aspartame (E951) as sweeteners, lemon flavouring (containing citral, lemon oil, lime oil, maltodextrin, vitamin E, xanthan gum,).

What dosage forms it comes in:

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

Sachet A contains the following active substances:

Macrogol 3350	100 g
Sodium sulphate anhydrous	7.5 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B contains the following active substances:

Ascorbic acid	4.7 g
Sodium ascorbate	5.9 g

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

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

The osmolarity of the final reconstituted solution is 560 mOsmol.

WARNINGS AND PRECAUTIONS

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 "Side Effects and What to Do About Them". Contact your doctor or pharmacist if you are concerned.

Before you use MOVIPREP, talk to your doctor or pharmacist if you have:

- kidney disease.
- heart failure.

- dehydration.
- acute flare of inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- phenylketonuria, (PKU - an inability to use the amino acid phenylalanine) - this product contains phenylalanine which can harm individuals with PKU.
- not enough glucose-6-phosphate dehydrogenase produced by your body.
- a history of electrolyte imbalance (e.g. hyponatremia).

Talk to your doctor about all the medications you are taking or planning to take (see Interactions with this medication)

Talk to your doctor if you have any tendency to regurgitate (bring up) food from your stomach into your esophagus or any tendency to accidentally inhale food or regurgitate food into the airways (breathing tube to the lung).

Talk to your doctor if you need to thicken fluids in order to swallow them safely. MOVIPREP contains polyethylene glycol (PEG), which may stop starch based food thickeners from working. This may cause certain mixtures to be watery and difficult to swallow.

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

Contact your doctor immediately and stop taking the drug if the following occurs while taking MOVIPREP:

- abdominal pain, bloating, swelling of the abdomen

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.

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

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 breastfeeding talk to your doctor before taking MOVIPREP.

INTERACTIONS WITH THIS MEDICATION

Drug interaction studies have not been performed for MOVIPREP.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including diuretics and

angiotensin converting enzyme inhibitor (ACE inhibitors- heart medication) and 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.

PROPER USE OF THIS MEDICATION

Usual dose: Adults 18 years of age and older:

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 water to make a one litre solution. This pack is therefore sufficient to make up 2 litres of MOVIPREP solution.

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.

How to drink MOVIPREP

This product can be taken as either as single dose or in 2 doses as per following:

Single dose:

Take the entire dose of 2 litres in the evening before the examination in the following steps:

- a) Drink the first litre of the Moviprep solution over one or two hours. Try to drink a glassful every 10-15 minutes.
- b) When you are ready, make up the second 1 litre solution and drink the same way, the evening before the examination.
- c) During the course of treatment, you are recommended to drink a further litre of clear liquid to prevent you from feeling thirsty and becoming dehydrated. Water, clear soup, fruit juice (without pulp, soft drink, tea or coffee (without milk) are all suitable. These drinks can be taken any time.

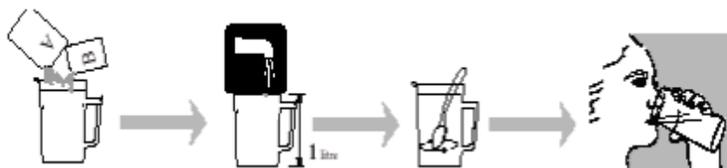
Divided Dose:

- a) Drink the first litre of the MOVIPREP solution over one or two hours the evening before the examination. Try to drink a glassful every 10-15 minutes.
- b) The next morning, make up and drink the second 1 litre solution and drink the same way.
- c) During the course of treatment, you are recommended to drink a further litre of clear liquid to prevent you from feeling thirsty and becoming dehydrated. Water, clear soup, fruit juice (without pulp), soft drink, tea or coffee (without milk) are all suitable. These drinks can be taken any time.

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 1 litre container.
- Pour 1 litre of water into 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.



Overdose:

If you think you have taken too much MOVIPREP, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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.

Missed Dose:

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

If you are taking other medicines take them at least one hour before or after taking MOVIPREP, otherwise they may flush through your system and will not work so well.

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

Children

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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. occurring in more than 1 in 10 patients who received the treatment) are: Abdominal pain, abdominal distension, tiredness, feeling generally unwell, soreness of the anus, and nausea.

Common side effects (i.e. occurring in less than 1 in 10 but more than 1 in 100 patients who received the treatment) are: Hunger, problems sleeping, dizziness, headache, vomiting, indigestion, upper abdominal pain, thirst and chills.

Uncommon side effects (i.e. occurring in less than 1 in 100 but more than 1 in 1,000 patients who received the treatment): Change to the levels of salts in the blood.

Blood 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.

Very low blood sodium levels can cause convulsions (fits).

Use of PEG-based products (polyethylene glycol) have resulted in seizures.

Other side effects that may occur include flatulence (wind), temporary increase in blood pressure, and some people may experience retching (straining to vomit).

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 taking MOVIPREP and contact your doctor immediately as these may be the signs of an allergic reaction or an electrolytes imbalance in the blood:

- rash or itching
- swelling of your face, ankles, throat, mouth or extremities
- palpitations (rapid heartbeat)
- extreme fatigue
- shortness of breath, difficulty in breathing

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect		Talk with your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
Common	Upper abdominal pain	X	
Uncommon	Electrolyte imbalance in		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect		Talk with your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
	the blood with symptoms such as palpitations, extreme fatigue, swelling of tissues, weakness Hypersensitivity (allergic) reaction with symptoms such as: rash, itching, hives, swelling of tissues, difficulty breathing	X	

If the following symptoms as hunger, problems sleeping, dizziness, headache, indigestion, thirst and chills become bothersome or persist, contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking MOVIPREP, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach 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 temperature between 5°C -25°C.

After you have dissolved MOVIPREP in the water, the solution may be stored (keeping covered) at temperature 15°C -25°C. It may also be stored in the fridge (2°C -8°C). Discard solution 24 hours after reconstitution.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Remember: Only a doctor can prescribe it for you. Never give it to someone else.

This leaflet does not contain the complete information about your medicine. If any questions remain unanswered or you are not sure about something, you should ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.aralez.com> or by contacting the sponsor, Aralez Pharmaceuticals Canada Inc. Mississauga, ON at: 1-866-391-4503

This leaflet was prepared by Aralez

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