1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MOVIPREP Powder for oral solution

Sachet A

Macrogol 3350

Sodium sulphate anhydrous

Sodium chloride

Potassium chloride

Sachet B

Ascorbic acid

Sodium ascorbate

Sugar free

Read all of this leaflet carefully before you start taking MOVIPREP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MOVIPREP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MOVIPREP is and what it is used for
2. What you need to know before you take MOVIPREP
3. How to take MOVIPREP
4. Possible side effects
5. How to store MOVIPREP
6. Contents of the pack and other information

1. What MOVIPREP is and what it is used for

MOVIPREP belongs to a group of medicines called laxatives.

MOVIPREP is intended for adults 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.

2. What you need to know before you take MOVIPREP

Do not take MOVIPREP

- if you are hypersensitive (allergic) to macrogol, sodium sulphate anhydrous, sodium chloride, potassium chloride, ascorbic acid, sodium ascorbate or any of the other ingredients of MOVIPREP (listed in section 6).
- if you have an obstruction in your intestine (gut).
- if you have a perforated gut wall.
- if you have a disorder of stomach emptying.
- if you have paralysis of the gut (often occurs after an operation on the abdomen).
- if you suffer from phenylketonuria. This is a hereditary inability of the body to use a particular amino acid (phenylalanine). MOVIPREP contains a source of phenylalanine.

- if your body is unable to produce enough glucose-6-phosphate dehydrogenase.
- if you have toxic megacolon (a severe complication of acute colitis).
- if you have impaired consciousness without medical supervision.

Warnings and precautions

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 this patient information leaflet. 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.
- Irregular heart beat (dysrhythmia).
- Dehydration.
- Acute flare of inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- Thyroid disease.

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

Children and adolescents

MOVIPREP should not be taken by children younger than 18 years.

Other medicines and MOVIPREP

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional 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.

MOVIPREP with food and drink

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 liquid intake.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MOVIPREP.

There are no data on the use of MOVIPREP during pregnancy or lactation and it should only be used if considered essential by the doctor.

Driving and using machines

MOVIPREP may cause dizziness. You should not drive or use machines when you are feeling dizzy.

It is not always possible to predict to what extent MOVIPREP may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MOVIPREP affects you (see section 4).

Important information about some of the ingredients of MOVIPREP

MOVIPREP contains 56,2 mmol of absorbable sodium per litre. To be taken into account by patients on a controlled sodium diet.

MOVIPREP contains 14,2 mmol of potassium per litre. To be taken into consideration by patients on a controlled potassium diet.

MOVIPREP contains aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take MOVIPREP

Always take MOVIPREP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

The usual dose of MOVIPREP is two litres of solution.

This MOVIPREP pack contains two clear bags each containing two pairs 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 two litres of MOVIPREP solution.

Your doctor will tell you how long your treatment with MOVIPREP will last. Do not stop treatment early. If you have the impression that the effect of MOVIPREP is too strong or too weak, tell your doctor or pharmacist.

Before you take MOVIPREP, please read the following instructions carefully. 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 MOVIPREP:

Your doctor, nurse or pharmacist will tell you when to take MOVIPREP. Your treatment with MOVIPREP must be completed before your clinical examination and can be taken either as:

- Divided dose: one litre of MOVIPREP in the evening before and one litre in the early morning of the day of the examination.

- Single dose: two litres in the evening before the examination or two litres of MOVIPREP in the early morning of the clinical procedure.

For procedures conducted when you are put to sleep (under general anaesthesia), ensure consumption of MOVIPREP as well as any other clear fluids has finished at least two

hours before the start of the clinical procedure.

For procedures conducted without the need to put you to sleep (general anaesthesia) ensure consumption of MOVIPREP as well as any other clear fluids has finished at least one hour before the start of the clinical procedure.

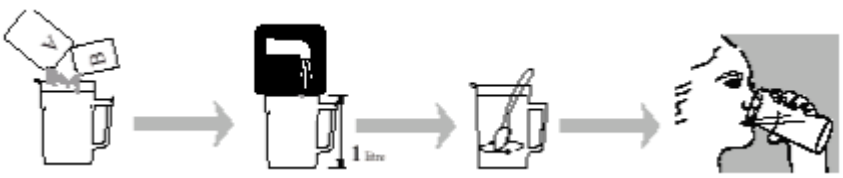
You should not drink any fluid (MOVIPREP or clear liquid) for at least one hour before the start of your colonoscopy.

You should allow sufficient time after your last drink to travel to the colonoscopy unit.

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 one litre container.
- Pour one 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.



How to drink MOVIPREP:

Drink the first litre of the 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 made up with the contents of the sachets A and B from the remaining pouch.

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 have the impression that the effect of MOVIPREP is too strong or too weak for you, talk to your doctor or pharmacist.

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, and consult your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MOVIPREP

If you forget to take MOVIPREP, take the dose as soon as you remember. If this is several hours after the time when you should have taken it, contact your doctor or pharmacist for advice. When taking MOVIPREP as divided doses, for examination while awake (without use of general anaesthesia), it is important that you complete your preparation at least an hour before your procedure or two hours before your examination when being put to sleep (with use of general anaesthesia). **Do not take a double dose to make up for forgotten individual doses.**

4. Possible side effects

MOVIPREP can have side effects.

Not all side effects reported for MOVIPREP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOVIPREP, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using MOVIPREP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MOVIPREP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the way your heart beats, for example, if you notice it is beating faster or unevenly (palpitations),
- extreme fatigue,
- difficulty breathing or shortness of breath,
- fits (convulsions) that could be due to low levels of sodium in the blood.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
It is normal to get diarrhoea when you take MOVIPREP.

Frequent side effects:

- stomach pain,
- stomach distension,
- tiredness,
- soreness or discomfort of the anus,
- thirst and nausea,
- hunger,
- problems sleeping,
- dizziness,
- vomiting,

- indigestion,
- chills,
- fever.

Less frequent side effects:

- headache,
- discomfort,
- difficulties swallowing,
- change in the levels of salts in the blood: decreased bicarbonate, increased or decreased calcium; increased or decreased chloride; decreased phosphorus,
- abnormal tests of the liver function.

Side effects with an unknown frequency:

- redness of the skin,
- dehydration,
- increase in blood pressure,
- wind (flatulence),
- straining to vomit (retching).

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

Allergic reactions may occur.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MOVIPREP.

5. How to store MOVIPREP

Store all medicines out of reach of children.

Store MOVIPREP sachets at or below 25 °C, in their original packaging.

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

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

WHAT MOVIPREP CONTAINS

The ingredients of MOVIPREP are contained in two separate sachets:

The active substances in each 112 g **Sachet A** of MOVIPREP contains:

Macrogol	100,000 g
Sodium sulphate anhydrous	7,500 g
Sodium chloride	2,691 g
Potassium chloride	1,015 g

The other ingredients are acesulfame potassium, aspartame, maltodextrin, citral, lemon oil, xanthan, vitamin E

Contains sweeteners: Aspartame 0,233 g, acesulfame potassium 0,117 g

Sugar free

The active substances in each 11 g **Sachet B** of MOVIPREP contains:

Sodium ascorbate	5,900 g
Ascorbic acid	4,700 g

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

Sodium	181,6 mmol/litre (of which not more than 56,2 mmol/litre is absorbable)
Chloride	59,8 mmol/litre
Sulphate	52,8 mmol/litre
Ascorbate	29,8 mmol/litre
Potassium	14,2 mmol/litre

What MOVIPREP looks like and contents of the pack

Sachet A contains a white to off-white free flowing powder with a characteristic lemon odour.

Sachet B contains a white to yellow free flowing powder.

Reconstituted solution: A clear to hazy, colourless to yellow solution when dissolved in one litre of water.

Sachet A: 112 g of powder is packed in a sachet made from laminate consisting of low density polyethylene, aluminium and paper.

Sachet B: 11 g of powder is packed in a sachet made from laminate consisting of low density polyethylene, aluminium and paper.

MOVIPREP contains four printed paper sachets (2 of sachet A and 2 of sachet B). One sachet A and one sachet B are packed together in a transparent polypropylene pouch; both are white sachets with blue print. One pack of MOVIPREP contains two of these pouches packed into an outer carton, white in colour with blue print.

MOVIPREP is available in pack sizes of 1, 10, 40, 80, 160 or 320 packs of a single treatment.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS2 12/11.5/0221

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