

MOVIPREP® ORANGE

Consumer Medicine Information

Please read this leaflet carefully because it contains important information for you. If you have any questions please ask your doctor or pharmacist.

What is MOVIPREP ORANGE?

MOVIPREP ORANGE is an orange flavoured powder contained in four sachets. There are two large sachets (Sachet A) and two small sachets (Sachet B). You need all these for one treatment.

What is MOVIPREP ORANGE used for?

You are taking MOVIPREP ORANGE to make your bowels clean so that they are ready for examination or surgery. MOVIPREP ORANGE works by emptying the contents of your bowels, so you should expect to have watery bowel movements.

Before you take MOVIPREP ORANGE

Do not take MOVIPREP ORANGE if your doctor has told you that you have:

- an obstruction in your intestine (gut)
- a perforated gut wall

- paralysis of the gut (often happens after an operation to the abdomen)
- if you suffer from phenylketonuria (This is a hereditary inability of the body to use a particular amino acid. MOVIPREP ORANGE contains a source of phenylalanine)
- your body is unable to produce enough glucose-6-phospho-dehydrogenase
- severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon
- an allergy to macrogol or other ingredients in the product.

If you are pregnant or breast feeding, talk to your doctor before you take MOVIPREP ORANGE.

If you are taking other oral medicines, speak to your doctor. Most other oral medicines should be taken at least one hour before or one hour after taking MOVIPREP ORANGE because they may be flushed through your digestive system and not work so well. However some medicines such as sustained release preparations or medicines with a narrow therapeutic window, such as the contraceptive mini-pill, may need to be taken more than one hour before or after MOVIPREP ORANGE. Contraceptive cover from the oral contraceptive pill is likely to be incomplete if it is taken at any time during the process of bowel cleansing with MOVIPREP ORANGE (an hour before the first dose of MOVIPREP ORANGE until after the investigation). Therefore an alternative method of contraception should be used for the length of the cycle when MOVIPREP ORANGE is taken.

Patients with insulin-dependent diabetes should consult their physician prior to use of MOVIPREP ORANGE. Only clear liquids (listed under 'How to drink MOVIPREP ORANGE') should be consumed during usage of MOVIPREP ORANGE, therefore insulin dosing should be balanced accordingly.

How to use MOVIPREP ORANGE

This pack contains 2 clear bags each containing two sachet pairs: sachet A and Sachet B.

Each pair of sachets (A and B) is to be dissolved in water to make one litre of solution. This pack is therefore enough to make up two litres of MOVIPREP ORANGE solution.

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

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

When to take MOVIPREP ORANGE

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

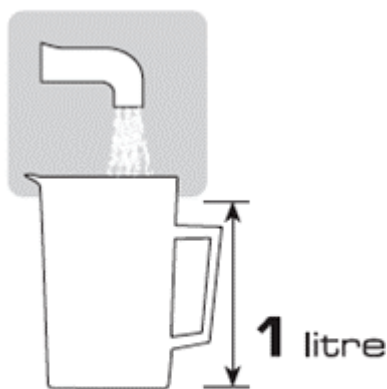
- divided as 1 litre of MOVIPREP ORANGE in the evening before and 1 litre in the early morning of the day of the examination, or
- 2 litres in the evening before the examination, or
- 2 litres early in the morning of an examination booked late in the same day.

Important: If you are taking MOVIPREP ORANGE as a divided dose or as 2 litres in the evening before the examination, do not take any solid food from when you start to take MOVIPREP ORANGE until after the examination.

If you are taking 2 litres of MOVIPREP in the morning of the day of your examination, do not take any solid food after 6 pm the evening before the examination until after the examination.

How to prepare MOVIPREP ORANGE

- Open one clear bag and remove Sachets A and B
- Add the contents of BOTH sachet A and B to a measuring container that holds 1 litre
- Add water into the container up to the 1 litre mark and stir until all the powder has dissolved and the MOVIPREP ORANGE solution is clear or slightly hazy. This may take up to 5 minutes.



How to drink MOVIPREP ORANGE

Drink the first litre of the MOVIPREP ORANGE 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 litre of MOVIPREP ORANGE solution made up with the contents of the Sachets A and B from the remaining bag.

During the course of this treatment drink a further one litre of clear liquid to prevent you from feeling very thirsty and becoming dehydrated. Clear liquids include: Water, clear soup, tea or coffee without milk or non-dairy creamer, all of the following liquids which are not coloured red or purple: fruit juices without pulp, carbonated or non carbonated soft drinks, fruit flavoured cordials Note: patients should not drink anything coloured red or purple.

What you should expect to happen

When you start drinking the MOVIPREP ORANGE 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 the MOVIPREP ORANGE 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.

Children

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

What about side effects?

Like all medicine, MOVIPREP ORANGE can have side effects.

You may feel full in the stomach, a little nauseous, have stomach pains or soreness around the anus, and if this happens take MOVIPREP ORANGE more slowly until these feelings stop. If the feelings do not stop, consult your pharmacist or doctor. There is a possibility of vomiting. If you feel other unpleasant side effects tell your doctor or pharmacist.

Blood sodium levels could also decrease, particularly if you take medicines that affect your kidneys, such as ACE inhibitors and diuretics used for the treatment of heart disease. Very low blood sodium levels can cause convulsions (fits).

If your blood sodium levels change, you may feel breathless, very thirsty with a severe headache, or get puffy ankles.

There have been rare reports of severe allergic reactions to Macrogol 3350 (an ingredient in MOVIPREP ORANGE). Signs of severe, life threatening allergic reaction include sudden signs of allergy, such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

If you experience any of these reactions, stop taking MOVIPREP ORANGE and tell your doctor immediately, or go to the Accident & Emergency department at your nearest hospital.

How to store MOVIPREP ORANGE

Keep MOVIPREP ORANGE sachets at room temperature (below 25°C), stored in their original packaging, and do not use after the expiry date on the label.

After you have dissolved MOVIPREP ORANGE in the water, the solution may be stored (keeping covered) at room temperature (below 25°C), or put it in the fridge (2-8°C). Do not freeze the solution and do not keep it for more than 24 hours.

Keep all medicines away from children.

What MOVIPREP ORANGE contains

Sachet A contains these 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 these active substances:

- Ascorbic acid 4.7 g
- Sodium ascorbate 5.9 g

The concentration of electrolyte ions when both sachets are made up to 1 litre of solution is as follows:

- Sodium 181.6 mmol/L (of which no more than 56.2 mmol is absorbable)
- Sulfate 52.8 mmol/L
- Chloride 59.8 mmol/L
- Potassium 14.2 mmol/L
- Ascorbate 29.8 mmol/L

MOVIPREP ORANGE also contains Orange Flavouring Powder SN760137 (ingredients include maltodextrin and glucose), aspartame and potassium acesulfame as sweeteners.

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