

MOVIPREP[®] Orange powder for oral solution

Macrogol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride.

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about Moviprep Orange powder for oral solution.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Moviprep Orange is used for

Moviprep Orange is a type of medicine called a bowel preparation. It makes 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 lots of watery bowel movements.

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 of these for one treatment.

Moviprep Orange is intended for adults (18 years of age and older), including the elderly, before any clinical procedure that needs a clean bowel.

Ask your doctor if you have any questions about why this medicine has been recommended for you.

Before you take Moviprep Orange

When you must not take it

Do not take Moviprep Orange:

- if you are allergic (hypersensitive) to the active ingredients or any of the other ingredients of Moviprep Orange (listed in 'Product Description')
- if you have a blockage in your intestine (gut)
- if you have an opening in the wall of your stomach or bowel (bowel perforation)
- if you experience problems with food and fluid emptying from your stomach (gastric retention)
- if you have paralysis of the gut (this 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 aspartame, a source of phenylalanine
- if your body is unable to produce enough glucose-6-phosphate dehydrogenase
- if you have severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon
- if you are very dehydrated

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, seek medical advice.

Before you start to take it

Make sure you are not dehydrated before the use of any bowel preparation. If you develop significant vomiting, or signs of fluid loss (dehydration) tell your doctor, see 'Side Effects' section.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor, pharmacist or nurse before taking Moviprep Orange if any of the points below apply to you. If you:

- have an allergy to any of the ingredients in Moviprep Orange
- have heart problems and/or heart rhythm problems
- have heart failure, severe kidney problems or are taking blood pressure medicine
- have kidney problems
- have problems with swallowing
- have a tendency to regurgitate swallowed drink, food or acid from the stomach
- have heart failure or heart disease including high blood pressure, irregular heartbeats or palpitations
- have thyroid disease
- are dehydrated
- have a decreased level of consciousness, unless you have suitable medical supervision
- are on a restricted sodium or restricted potassium diet
- have epilepsy or a history of convulsions.

If you experience (blood) vomiting followed by sudden chest, neck or abdominal pain, difficulty swallowing or difficulty breathing when taking Moviprep Orange, stop taking medicine and promptly contact your doctor.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

It is not known if Moviprep Orange passes into your breast milk. You and your doctor should decide if you should take Moviprep Orange while breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking Moviprep Orange.

Taking other medicines

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines (e.g. oral contraceptives, diuretics, calcium channel blockers, corticosteroids), as well as any you get without a prescription from your pharmacy, supermarket or health food shop.

Don't take oral medicines within one hour (i.e. includes one hour before administration, as well as during administration and one hour after administration) of taking Moviprep Orange, as they may be flushed through without working properly. 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. Therefore an alternative method of contraception should be used for the length of the cycle when Moviprep Orange is taken.

If you have insulin-dependent diabetes, talk to your doctor before you take Moviprep Orange. Once you start taking

Moviprep Orange, you can only drink the clear fluids (listed under 'Moviprep Orange with food and drink') so you will need to adjust your insulin dose.

Your doctor may tell you to temporarily stop some medicines before your procedure. Follow their advice.

If you need to thicken fluids in order to swallow them safely, Moviprep Orange may counteract the effect of the thickener.

Moviprep Orange with food and drink

Your doctor may ask you to change your diet a few days before the procedure, for example, asking you to avoid high-fibre foods. When taking Moviprep Orange you should continue to drink plenty of clear fluids. The fluid content of Moviprep Orange does not replace your regular fluid intake.

Examples of clear fluids are water, clear soups, herbal tea, black tea or coffee (without milk), soft drinks/diluted cordials and clear fruit juices (without pulp).

Important: Do not drink alcohol, milk, anything coloured red or purple (e.g. blackcurrant juice) or any other drinks containing pulp material and do not eat while taking Moviprep Orange and until after your clinical procedure.

Two-day split dosing schedule and day before dosing schedule

Your doctor will give advice on what you can eat the day before the procedure. Once you start taking Moviprep Orange, you can't eat any food, you can only drink clear fluids.

Morning only dosing schedule

Do not eat any food after 6 pm the evening before your procedure. You may only drink clear fluids from this time. No breakfast is allowed on the morning of the clinical procedure.

Your Doctor may give you additional dietary advice which you should follow.

How to take Moviprep Orange

Unless your doctor has given you different instructions, please follow these dosage and dietary instructions. This will help you get the best results from Moviprep Orange. Check with your doctor, pharmacist or nurse if you are not sure what to do.

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 may prescribe the two-day split dosing schedule, the morning only dosing schedule or the day before dosing schedule, depending on the time of your clinical procedure.

Your doctor will tell you which dosing schedule to follow. Your treatment with Moviprep Orange must be completed before your clinical procedure.

You take this treatment as divided doses, as described below (the times given are only suggestions; your doctor may tell you different times).

Two-day split dosing schedule

Dose 1. Drink 1000 mL of Moviprep Orange in the evening (at approximately 6pm) before the clinical procedure, followed by an extra 500 mL of clear fluid

Dose 2. Drink 1000 mL of Moviprep Orange (at approximately 6am) on the morning of the clinical procedure, followed by an extra 500 mL of clear fluid.

Morning only dosing schedule

Dose 1. Drink 1000 mL of Moviprep Orange on the morning (at approximately 5 am) of the clinical procedure, followed by an extra 500 mL of clear fluid.

Dose 2. Drink 1000 mL of Moviprep Orange at the time your doctor told you, followed by an additional 500 mL of clear fluid.

Day before dosing schedule

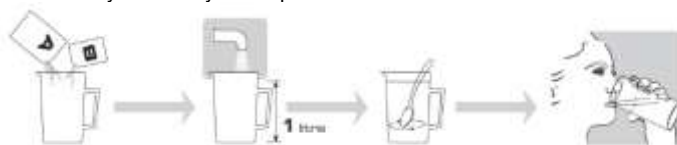
Dose 1. Drink 1000 mL of Moviprep Orange in the evening (at approximately 6pm) before the clinical procedure, followed by an extra 500 mL of clear fluid.

Dose 2. Drink 1000 mL of Moviprep Orange later the same evening, at the time your doctor told you to, followed by an extra 500 mL of clear fluid.

Your doctor will tell you which dosing schedule to follow.

How to prepare Moviprep Orange Dose 1

- 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 (not chilled) 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.



You can prepare Moviprep Orange solution before you need to drink it, and store it in the fridge. It may be easier to drink if chilled. **DO NOT add any other ingredients to the doses.**

How to drink Moviprep Orange Dose 1

Drink the first 1000 mL of Moviprep Orange solution over one to two hours. Try and drink a glassful every 10-15 minutes.

Drink an extra 500 mL of clear fluid. You can alternate the clear fluid with the Moviprep Orange if you wish. Water, clear soup, diluted cordial/clear fruit juice (without pulp), herbal tea, black tea or coffee (without milk) are all suitable.

How to prepare Moviprep Orange Dose 2

- When you are ready, prepare the second litre of Moviprep Orange solution made up with the contents of the Sachets A and B from the remaining bag. Follow the instructions for Dose 1 (above).

How to drink Moviprep Orange Dose 2

Drink the second 1000 mL of Moviprep Orange solution over one to two hours. Try and drink a glassful every 10-15 minutes.

Drink an extra 500 mL of clear fluid. You can alternate the clear fluid with the Moviprep Orange if you wish. Water, clear soup, diluted cordial/clear fruit juice (without pulp), herbal tea, black tea or coffee (without milk) are all suitable.

In addition to Moviprep Orange and the 500 mL clear fluid after each dose, you can drink extra clear fluid as needed to avoid thirst. Drinking clear fluids will help prevent fluid loss (dehydration). You must stop drinking all fluids **at least 2 hours** before your clinical procedure. Your doctor should tell you your 'NIL BY MOUTH' time.

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 that the Moviprep Orange solution is working. You may have stomach area bloating before you have your first bowel movement.

If you follow these instructions, your bowel will be clean, and this will help you to have a successful clinical procedure. You should allow sufficient time after your bowel movements have subsided to travel to the clinic/ hospital.

If you forget to take it

If you forget to take Moviprep Orange as instructed, take it as soon as you realise you have not taken it and contact your doctor, pharmacist or nurse for advice before the clinical procedure. It is important that you have allowed sufficient time to complete your course of Moviprep Orange in order to ensure your bowel is fully cleaned at least 2 hours before the clinical procedure.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to the Accident and Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much Moviprep Orange.

While you are using Moviprep Orange

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not use Moviprep Orange for any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell a doctor or pharmacist as soon as possible if you do not feel well while you are using Moviprep Orange.

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask a doctor or pharmacist to answer any questions that you may have.

It is normal to get diarrhoea when you take Moviprep Orange. If you do not have a bowel movement within 6 hours of taking Moviprep Orange, stop the intake and contact your doctor immediately.

As with other medicines there is a small risk of serious allergic reactions. Stop taking Moviprep Orange and tell your doctor immediately or go to the Accident & Emergency department of your nearest hospital if you notice any of the following side effects, as these may be symptoms of a severe allergic reaction:

- extreme fatigue
- palpitations
- sudden or severe itching, skin rash, hives
- shortness of breath, asthma, wheezing
- swelling of your face, lips or tongue (which may make swallowing or breathing difficult), ankles or other part of your body

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

- seizure

If you experience sudden abdominal pain or rectal bleeding when taking Moviprep Orange for bowel preparation, contact your doctor or seek medical advice immediately.

Very common side effects (may affect more than 1 in 10 people):

Abdominal pain, abdominal distension, tiredness, feeling generally unwell, soreness of the anus, nausea and fever.

Common side effects (may affect up to 1 in 10 people): Hunger, problems sleeping, dizziness, headache, vomiting, indigestion, thirst and chills.

Uncommon side effects (may affect up to 1 in 100 people): Discomfort, difficulties swallowing, and changes to tests of liver function.

The following side effects have sometimes been seen but it is not known how often they occur because the frequency cannot be estimated from the available data: flatulence (wind), temporary increase in blood pressure, irregular heart rhythm or palpitations, dehydration, retching (straining to vomit), oesophageal rupture due to vomiting, 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.

If you are over 65 years of age, you may have an increased chance of getting side effects.

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 section. Contact your doctor, pharmacist or nurse if you are concerned.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use this medicine after the expiry date which is stated on the sachets and carton, after “EXP”.

The expiry date refers to the last day of that month.

Please note that the expiry dates may be different for each of the sachets and carton.

Before use store Moviprep Orange sachets below 25°C.

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

Do not store Moviprep Orange or any other medicines in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

What Moviprep Orange contains

Sachet A contains the following active substances:

Macrogol 3350	100 g
Sodium sulfate	7.5 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet A also contains 175 mg of aspartame (E951).

Sachet B contains the following active substances:

Sodium ascorbate	5.9 g
Ascorbic acid	4.7 g

The inactive ingredients in Moviprep Orange are: orange flavour (containing maltodextrin and glucose), and the sweeteners aspartame and potassium acesulfame.

The complete treatment contains 8.4 g of sodium and 1.1 g of potassium

Supplier

Moviprep Orange is supplied in Australia by:

Norgine Pty Ltd
Suite 3.01, Building A
20 Rodborough Road
Frenchs Forest NSW 2086
AUSTRALIA
Phone: 1800 766 936
www.norgine.com.au

Moviprep Orange is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
58 Richard Pearse Drive
Mangere, Auckland
Phone: (09) 918 5100
Medical Enquiries 0800 404 178

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