

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

MOLATIVE ORANGE, powder for oral solution

Macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride

Contains sweetener (Acesulfame Potassium 10,05 mg per sachet)

Sugar free

Read all of this leaflet carefully because it contains important information for you

MOLATIVE ORANGE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MOLATIVE ORANGE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MOLATIVE ORANGE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

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

1. What MOLATIVE ORANGE is and what it is used for

MOLATIVE ORANGE contains macrogol 3350 and the electrolytes sodium chloride, sodium hydrogen carbonate and potassium chloride.

Macrogol 3350 is a laxative used for the treatment of constipation in adults, adolescents and the elderly, especially if you have been constipated for a long time. It is not recommended for children below 12 years of age. The electrolytes help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

2. What you need to know before you take MOLATIVE ORANGE

Do not take MOLATIVE ORANGE:

- if you are hypersensitive (allergic) to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients of this medicine (listed in section 6)
- if you have a perforation in the wall of your intestine
- if you have a blockage in your intestine
- if you have paralysis of the intestine (for example, your intestines may stop working due to intestinal surgery or severe infection)
- if you have gastric retention (symptoms generally include nausea, vomiting, bloating, and upper abdominal discomfort)
- if you have peptic ulceration (a sore that develops on the lining of the oesophagus, stomach or small intestine with symptoms such as upper abdominal pain)
- if you have ulcerative colitis, Crohn's disease or toxic megacolon
- if you are younger than 12 years of age.

Warnings and precautions

Take special care with MOLATIVE ORANGE:

- If you have stomach-ache, feel nauseous or are vomiting.
- Consult your doctor before using MOLATIVE ORANGE if you notice sudden change in your bowel habits that persists for a period longer than 2 weeks.
- Consult your doctor if you experience rectal bleeding or do not have a bowel movement after using MOLATIVE ORANGE.
- Do not use MOLATIVE ORANGE frequently or for long periods as this may cause dependence and a loss of

normal bowel function.

- As stomach problems occur most commonly, and frequent/loose watery stools (diarrhoea) usually responds to dose reduction.
- If you are on a low salt diet as MOLATIVE ORANGE contains salt.

When taking MOLATIVE ORANGE you should continue to take plenty of fluids. The fluid content of MOLATIVE ORANGE should not replace your regular liquid intake.

Mild side effects are possible but if you develop any symptoms which may indicate fluid or electrolyte imbalances such as swelling, shortness of breath, increasing tiredness, dehydration and heart failure, you should stop taking MOLATIVE ORANGE and contact your healthcare provider.

The absorption of other medicines may be temporarily reduced by MOLATIVE ORANGE.

Children and adolescents

MOLATIVE ORANGE is not recommended for children under 12 years of age (see “Do not take MOLATIVE ORANGE”).

Other medicines and MOLATIVE ORANGE

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

The absorption of other medicines may be temporarily reduced by MOLATIVE ORANGE.

Some medicines, e.g. anti-epileptics, may not work as effectively if they are taken at the same time as MOLATIVE ORANGE.

MOLATIVE ORANGE with food and drink

Food and drink have no influence on the effect of MOLATIVE ORANGE.

Pregnancy, breastfeeding and fertility

MOLATIVE ORANGE can be taken during pregnancy and whilst breastfeeding.

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 MOLATIVE ORANGE.

Driving and using machines

MOLATIVE ORANGE has no effect on the ability to drive or use machines.

It is not always possible to predict to what extent MOLATIVE ORANGE may interfere with your daily activities.

You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which MOLATIVE ORANGE affects you.

MOLATIVE ORANGE contains sodium

This medicine contains 187 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to approximately 9 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need three or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take MOLATIVE ORANGE

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

Always take MOLATIVE ORANGE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults, adolescents and the elderly: 1 sachet 1 to 3 times a day.

For extended use, 1 or 2 sachets a day.

Take one sachet 1 to 3 times a day according to the severity of your constipation. The dose may be adjusted up or down, according to how hard or soft your stool is.

When MOLATIVE ORANGE is first started, it may take a few days to start working.

MOLATIVE ORANGE should be made up by dissolving the contents of one sachet in a glass of water (125 ml). Stir well until all the powder has dissolved.

Duration of treatment

The course of treatment for constipation does not normally last longer than 2 weeks. Your treatment may last for longer than two weeks if you have ongoing constipation, or a disease that causes constipation (such as Parkinson's disease or multiple sclerosis), or if you are taking other regular medicines that can cause constipation. In these cases, your doctor may reduce your dose to one sachet taken one or two times daily.

If you have the impression that the effect of MOLATIVE ORANGE is too strong or too weak, talk to your doctor or pharmacist.

If you take more MOLATIVE ORANGE than you should

You may develop diarrhoea. Stop taking MOLATIVE ORANGE until the diarrhoea clears. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MOLATIVE ORANGE

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MOLATIVE ORANGE can have side effects.

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

If any of the following happens, stop using MOLATIVE ORANGE 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 MOLATIVE ORANGE. 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:

- signs of a change in your body's fluid or electrolyte levels, such as swelling (mainly in the ankles), feeling fatigued, dehydration or increased thirst with headache. These symptoms may be a sign that the potassium levels in your blood are higher or lower than normal.

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

Tell your doctor if you notice any of the following:

- redness of the skin
- abdominal pain
- mild diarrhoea
- vomiting
- feeling bloated
- indigestion
- nausea
- suffering from wind
- swelling of your abdomen
- stomach rumbling
- soreness of the anus.

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 via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MOLATIVE ORANGE.

5. How to store MOLATIVE ORANGE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

- Store at or below 25 °C in its original container.
- Reconstituted solution: Store covered in a refrigerator at 2 – 8 °C. Discard any solution not used within 6 hours after reconstitution.
- Do not use this medicine if you notice that any of the sachets is damaged.
- Do not take after the expiry date printed on the pack.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What MOLATIVE ORANGE contains

The active substances are macrogol 3350 (13,125 g), sodium chloride (350,7 mg), sodium hydrogen carbonate (178,5 mg) and potassium chloride (46,6 mg).

The other ingredients are acesulfame potassium (E950) and orange flavour flavouring (containing maltodextrin and propylene glycol (E1520)).

What MOLATIVE ORANGE looks like and contents of the pack

MOLATIVE ORANGE is a white powder that is packed in sachets. It has an orange taste and smell.

MOLATIVE ORANGE powder for oral solution are packed in a sachet foil composed of paper, low density polyethylene and aluminium.

Available pack sizes 2, 8, 10, 20, 30, 50 or 100 sachets packed in outer carton container. Not all pack sizes to be

marketed.

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