

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

MOLATIVE PAEDIATRIC, powder for oral solution

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

Sugar free

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

MOLATIVE PAEDIATRIC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MOLATIVE PAEDIATRIC carefully to get the best results from it.

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

What is in this leaflet

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

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

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

MOLATIVE PAEDIATRIC is a laxative used for treating constipation in children aged 2 to 11 years.

2. What you need to know before you give MOLATIVE PAEDIATRIC

Do not give MOLATIVE PAEDIATRIC:

Do not give MOLATIVE PAEDIATRIC if your doctor has told you that your child has:

- hypersensitivity (allergy) to any of the ingredients of MOLATIVE PAEDIATRIC (listed in section 6)
- a hole or leak in the wall of the intestine
- a blockage in the intestine (gut)
- paralysis of the bowel (for example, their intestines may stop working due to intestinal surgery or severe infection)
- severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon.

Warnings and precautions

Take special care with MOLATIVE PAEDIATRIC:

- If your child has stomach-ache, feels nauseous or is vomiting.
- Consult your doctor before giving your child MOLATIVE PAEDIATRIC if you notice a sudden change in their bowel habits that persists for a period longer than 2 weeks.
- Consult your doctor if your child experiences rectal bleeding or does not have a bowel movement after using MOLATIVE PAEDIATRIC.
- Do not give your child MOLATIVE PAEDIATRIC frequently or for long periods as this may cause dependence and a loss of normal bowel function.
- Your child should continue to take plenty of fluids. The fluid content of MOLATIVE PAEDIATRIC should not replace your child's regular liquid intake.
- Mild side effects are possible but if your child develops any symptoms which may indicate fluid or electrolyte imbalances such as swelling, shortness of breath, increasing tiredness, dehydration and heart failure, you should stop giving MOLATIVE PAEDIATRIC to your child and contact your healthcare provider.
- The absorption of other medicines your child is taking may be temporarily reduced by MOLATIVE PAEDIATRIC.

MOLATIVE PAEDIATRIC is not recommended for children below 2 years of age.

Other medicines and MOLATIVE PAEDIATRIC

Always tell your healthcare professional if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

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

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 MOLATIVE PAEDIATRIC.

Driving and using machines

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

It is not always possible to predict to what extent MOLATIVE PAEDIATRIC 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 PAEDIATRIC affects you.

MOLATIVE PAEDIATRIC contains sodium

This medicine contains 93,4 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to approximately 4,6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to give MOLATIVE PAEDIATRIC

Do not share medicines prescribed for your child with any other person.

Always give MOLATIVE PAEDIATRIC 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.

Dissolve the contents of one sachet in approximately 62,5 ml ($\frac{1}{4}$ of a glass) of water. Stir well until all the powder

has dissolved and give it to your child to drink.

The dose of MOLATIVE PAEDIATRIC depends on the age of the child and their response to treatment.

- As a starting dose, children aged 2 to 6 years should be given 1 sachet (=1 dose) each day.
- Children aged 7 to 11 should be given 2 sachets each day.
- The doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement.

Normally, no more than 4 sachets are required to be taken in one day.

The correct number of sachets may be reconstituted in advance and kept covered and refrigerated for up to 24 hours. For example, 4 sachets can be made up into 250 ml of water.

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

If your child takes more MOLATIVE PAEDIATRIC than they should

Your child may develop excessive diarrhoea. If this occurs, your child should stop taking MOLATIVE PAEDIATRIC and drink plenty of fluids. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to give MOLATIVE PAEDIATRIC

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

4. Possible side effects

MOLATIVE PAEDIATRIC can have side effects.

Not all side effects reported for MOLATIVE PAEDIATRIC are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking MOLATIVE PAEDIATRIC, please consult their healthcare provider for advice.

If any of the following happens, stop giving MOLATIVE PAEDIATRIC 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 your child have them, they may have had a serious reaction to MOLATIVE PAEDIATRIC. Your child 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:

- breathlessness or difficulty in breathing
- signs of a change in the fluid or electrolyte levels your child's body, 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 child's blood are higher or lower than normal.

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

Tell your doctor if you notice any of the following:

Frequent

- abdominal pain
- stomach rumbling
- diarrhoea
- vomiting
- nausea
- soreness of the anus

Less frequent

- swelling of the abdomen

- feeling bloated
- flatulence

Unknown frequency

- shortness of breath
- redness of the skin
- indigestion
- inflammation at or near the anus
- hives
- low or high potassium levels

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

Reporting of side effects

If your child gets 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 PAEDIATRIC.

5. How to store MOLATIVE PAEDIATRIC

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 for up to 24 hours. Discard any solution not used within 24 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 PAEDIATRIC contains

The active substances are macrogol 3350 (6,563 g), sodium chloride (175,4 mg), sodium hydrogen carbonate (89,3 mg) and potassium chloride (25,1 mg).

No inactive ingredients.

What MOLATIVE PAEDIATRIC looks like and contents of the pack

White powder. When the powder is completely dissolved in a quarter glass of water the solution is clear or slightly hazy.

The foil sachet is composed of paper, low density polyethylene and aluminium.

Each carton contains 2, 6, 8, 10, 20, 30, 50 or 100 sachets.

Not all packs and pack sizes are necessarily marketed.

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