

MOLAXOLE®

macrogol 3350/sodium chloride/

sodium bicarbonate/potassium chloride powder for oral solution

What is in this leaflet

Please read this leaflet carefully before you start taking MOLAXOLE.

This leaflet answers some common questions about MOLAXOLE.

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

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 MOLAXOLE is used for

MOLAXOLE helps you to have a comfortable bowel movement even if you have been constipated for a long time.

MOLAXOLE also works in very bad constipation (called faecal impaction), as determined by your doctor.

Macrogol 3350 increases the volume of faeces by binding water leading to a normalisation of motility in the colon. The physiological consequences are an increased movement of the softened stools and easing of defaecation. The salts in the formulation help maintain the body's normal salt and water balance.

Each sachet contains 13.8 g of MOLAXOLE powder. You add the powder to water to make a drink.

This medicine is available without a doctor's prescription. However, you still need to take MOLAXOLE

carefully to get the best results from it.

Before you take MOLAXOLE

When you must not take it

Do not take MOLAXOLE if you have an allergy to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

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

- **An obstruction in your intestine (gut).**
- **A perforated gut wall.**
- **Severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.**
- **Paralysis of the bowel.**

Do not take MOLAXOLE after the expiry date printed on the pack. If you use this medicine after the expiry date has passed, it may not work as well.

Do not take MOLAXOLE if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking MOLAXOLE,

consult your doctor or pharmacist.

Before you start to take it

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

Tell your doctor if you have or have had any of the medical conditions relating to the heart or blood pressure (cardiovascular).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor or pharmacist will discuss the possible risks and benefits of taking MOLAXOLE during pregnancy or breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MOLAXOLE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking MOLAXOLE.

Laxative products such as MOLAXOLE have the potential to interact with other medicines by altering their absorption. Some medicine, e.g. anti-epileptics, may not work as effectively during use with MOLAXOLE. It may be necessary to closely monitor your medications when you commence or cease taking MOLAXOLE regularly. It is important that you discuss this with your pharmacist or doctor.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MOLOXLE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the sachet ask your doctor or pharmacist for help.

How much to take

Dosage in adults and children over 12 years of age:

Constipation

The recommended dose of MOLAXOLE is 1 sachet a day. This may be increased up to 3 sachets daily if necessary.

Faecal impaction as diagnosed by a doctor

The dose is 8 sachets a day taken within 6 hours. You may need to take this dose for up to 3 days.

Patients with impaired cardiovascular function

If you have a heart condition, do not take more than 2 sachets in any one hour.

Patients with renal insufficiency

No dosage change is necessary for treatment of either constipation or faecal impaction.

Do not exceed the recommended dose.

If you are not sure of the correct dose or how to use this medicine, ask your pharmacist or doctor.

How to take it

Mix the contents of 1 sachet with a 1/2 glass of water (about 125 mL). Stir well until all the powder has dissolved and drink it. If you like,

you can add fruit juice or fruit syrup immediately before drinking.

If you are taking MOLAXOLE for the treatment of faecal impaction, you can mix 8 sachets in 1 litre of water. The solution can then be stored in the fridge.

Drink plenty of water and increase fibre in diet except in cases of medication-induced constipation.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you miss a dose, take MOLAXOLE when the next dose is due. Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking MOLAXOLE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MOLAXOLE.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking] this medicine, tell your doctor. Your doctor can discuss with you the risks of using it while you are pregnant

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take MOLAXOLE to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

Prolonged use of laxatives is undesirable and may lead to dependence. If symptoms persist, seek medical advice

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MOLAXOLE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much MOLAXOLE and get bad diarrhoea, stop taking MOLAXOLE until it clears. If constipation recurs, you should check with your doctor or pharmacist. If you are worried, contact your doctor or pharmacist.

Symptoms of an overdose may include diarrhoea.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MOLAXOLE.

This medicine helps most people with constipation but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Stomach-ache or rumbles
- Bloating
- Feeling sick
- Diarrhoea (especially when starting to take MOLAXOLE)

Stop taking MOLAXOLE and tell your doctor as soon as possible if you experience any of the following:

- Weakness
- Breathlessness
- Feeling very thirsty with a headache
- Puffy ankles
- Allergic reaction, symptoms may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using MOLAXOLE

Storage

Keep MOLAXOLE in a cool dry place where the temperature stays below 25 °C. Store in the original package in order to protect from moisture.

Once you have made up MOLAXOLE in water, cover it well and store in the fridge (2 °C to 8 °C). Do not freeze. Throw away any solution not used within a 6 hour period.

Keep it where young children cannot reach it.

Do not store MOLAXOLE or any other medicine 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.

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.

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

White, crystalline powder contained in single-dose sachets.

Ingredients

Active ingredient(s):
Each 13.8 g sachet of MOLAXOLE contains:

- macrogol 3350 13.125 g
- sodium chloride 350.7 mg
- sodium bicarbonate 178.5 mg
- potassium chloride 46.6 mg

When it is made into a drink with 125 mL water, each sachet gives the equivalent of:

- sodium 65 mmol/L
- chloride 53 mmol/L
- bicarbonate 17 mmol/L
- potassium 5.4 mmol/L

Each MOLAXOLE sachet contains 26 mg of elemental potassium and 187 mg of elemental sodium.

Inactive ingredient(s):
MOLAXOLE also contains:

- lemon flavour
- acesulfame potassium as a sweetener,

There are 30 sachets in a box.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

MOLAXOLE is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

25 July 2022

Molaxole® is a Viatrix company trade mark.