

MOLAXOLE[®] Powder for oral solution

macrogol 3350/sodium chloride/sodium bicarbonate/
potassium chloride

Consumer Medicine Information

What is in this leaflet

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.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

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.

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.

Do not give this medicine to a child under the age of 12 years.

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 or pharmacist if you are pregnant or plan to become pregnant, or are breastfeeding. 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 any that you can get without a

prescription from your pharmacy, supermarket or health food shop.

Laxative products such as MOLAXOLE have the potential to interact with other medicines by altering their absorption. 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 MOLAXOLE

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 box, 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.

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.

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.

If you take too much (overdose)

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.

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

Things to be careful of

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

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may not experience any of them.

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 if you experience any of the following:

- Weakness
- Breathless

- Very thirsty with a headache
- Puffy ankles

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.

Product description

Ingredients

Active ingredients:

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

Other ingredients:

MOLAXOLE also contains lemon flavour and acesulfame potassium as a sweetener.

There are 2, 6, 8, 10, 20 or 30 sachets in a box*. Each sachet contains 13.8 g of MOLAXOLE powder. You add the powder to water to make a drink.

Sponsor

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 314 527

www.mylan.com.au

Mylan New Zealand Limited

Auckland, NZ

Phone: 0800 168 169

Distributor

Alphapharm Pty Ltd (Mylan Australia)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 314 527

www.mylan.com.au

Mylan New Zealand Limited

Auckland, NZ

Phone: 0800 168 169

This leaflet was prepared in July 2018.

AUST R 213018

Version 7

*Not all pack sizes are marketed.