

New Zealand Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MOLAXOLE®?

MOLAXOLE® contains the active ingredient macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride. 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.

For more information, see Section [1. Why am I using MOLAXOLE®?](#) in the full CMI.

2. What should I know before I use MOLAXOLE®?

Do not use if you have ever had an allergic reaction to MOLAXOLE® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MOLAXOLE®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOLAXOLE® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MOLAXOLE®?

- Dosage in adults and children over 12 years of age
- 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.

More instructions can be found in Section [4. How do I use MOLAXOLE®?](#) in the full CMI.

5. What should I know while using MOLAXOLE®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MOLAXOLE®.• Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how MOLAXOLE® affects you.• Prolonged use of laxatives is undesirable and may lead to dependence. If symptoms persist, seek medical advice.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using MOLAXOLE®?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. This medicine helps most people with constipation, but it may have unwanted side effects in a few people.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MOLAXOLE®

Active ingredient(s): *macrogol 3350/sodium chloride/sodium bicarbonate/potassium chloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOLAXOLE®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MOLAXOLE®.**

Where to find information in this leaflet:

- [1. Why am I using MOLAXOLE® ?](#)
- [2. What should I know before I use MOLAXOLE® ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MOLAXOLE® ?](#)
- [5. What should I know while using MOLAXOLE® ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MOLAXOLE®?

MOLAXOLE® contains the active macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride.

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.

2. What should I know before I use MOLAXOLE®?

Warnings

Do not use MOLAXOLE® if:

- you have an allergy to any of the ingredients listed at the end of this leaflet.
- you have an allergy to any other medicines, foods, preservatives or dyes.
- Always check the ingredients to make sure you can use this medicine.

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
- 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.

Check with your doctor if you:

- 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
- allergies to any other medicines, foods, preservatives or dyes
- have had any of the medical conditions relating to the heart or blood pressure (cardiovascular)
- 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®.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MOLAXOLE®.

4. How do I use MOLAXOLE®?

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 MOLAXOLE®

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 liter 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.

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

When to take MOLAXOLE®

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 MOLAXOLE®

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

If you forget to use MOLAXOLE®

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.

If you use too much MOLAXOLE®

If you think that you have used too much MOLAXOLE®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using MOLAXOLE®?

Things you should do

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

Call your doctor straight away if you:

- are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MOLAXOLE®.
- are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery. Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using MOLAXOLE®.
- become pregnant while taking] this medicine, tell your doctor. Your doctor can discuss with you the risks of using it while you are pregnant.

- 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 your doctor's appointments so that your progress can be checked.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MOLAXOLE® affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

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

When to discard your medicine (as relevant)

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Stomach-ache or rumbles • Bloating • Feeling sick • Diarrhoea (especially when starting to take MOLAXOLE®) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Stop taking MOLAXOLE® and call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What MOLAXOLE® contains:

Active ingredient (main ingredient)	<p>Each 13.8 g sachet of MOLAXOLE® contains:</p> <ul style="list-style-type: none">• Macrogol 3350 13.125 g• Sodium chloride 350.7 mg• Sodium bicarbonate 178.5 mg• Potassium chloride 46.6 mg <p>When it is made into a drink with 125 mL water, each sachet gives the equivalent of:</p> <ul style="list-style-type: none">• sodium 65 mmol/L• chloride 53 mmol/L• bicarbonate 17 mmol/L• potassium 5.4 mmol/L <p>Each MOLAXOLE® sachet contains 26 mg of elemental potassium and 187 mg of elemental sodium.</p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lemon flavour• acesulfame potassium as a sweetener

Do not take this medicine if you are allergic to any of these ingredients.

What MOLAXOLE® looks like

MOLAXOLE® looks like a white, crystalline powder contained in single-dose sachets.

Available in 30 sachets in a box

Medsafe File reference: TT50-9451

Who distributes MOLAXOLE®

1. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics, 58 Richard Pearse Drive, Airport Oaks, Mangere, AUCKLAND 2022
2. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics, 6 Te Kapua Drive, Mangere, AUCKLAND 2022

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