Package leaflet: Information for the user

Molaxole® Powder for oral solution,
Macrogol 3350
Sodium chloride
Sodium hydrogen carbonate
Potassium chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks of constipation. If you are treated for very bad constipation (called faecal impaction) you should follow your doctor's instruction.

What is in this leaflet:

1. What Molaxole is and what it is used for

Molaxole helps you to have a comfortable bowel movement even if you have been constipated for a long time. After consulting a doctor, Molaxole can also be used for treatment of very bad constipation (called faecal impaction).

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 defecation. The salts in the formulation help maintain the body´s normal salt and water balance.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks of constipation. If you are treated for very bad constipation (called faecal impaction) you should follow your doctor's instruction.

2. What you need to know before you take Molaxole

Do not take Molaxole

- if you are allergic to any of the active substances macrogol, sodium chloride, potassium chloride or sodium hydrogen carbonate or any of the other ingredients of this medicine (listed in section 6)
- if you have an obstruction in the intestine (gut), a perforated gut wall or severe inflammatory bowel disease like ulcerative colitis, Crohn´s disease, toxic megacolon or ileus.

Warnings and Precautions
Talk to your doctor or pharmacist before taking Molaxole.

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

If you develop side effects, such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems, you should stop taking Molaxole and tell your doctor immediately.

Do not take Molaxole for longer periods of time unless you have been instructed to do so by your doctor for example if you take drugs that can cause constipation or if you have a disease which cause constipation for example Parkinson's disease or multiple sclerosis (MS).

Children
Do not give this medicine to children below 12 years of age.

Other medicines and Molaxole
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines, e.g. anti-epileptics may not work as effectively during use with Moxalole.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Molaxole can be used during pregnancy and breast-feeding.

Driving and using machines
There is no effect on the ability to drive or use machines.

Molaxole contains sodium
This medicine contains 187 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 9.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Molaxole

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for constipation is:
1 sachet one to three times daily. Normal dose for most patients is 1-2 sachets per day. Depending on the individual response 3 sachets per day might be needed. The dose depends on the severity of your constipation. The dose can be adjusted down to the lowest effective dose after a couple of days. The time of the treatment is normally 2 weeks. If the symptoms persist after 2 weeks treatment contact your doctor.

Mix the content of 1 sachet with a ½ glass of water (about 125 ml). Stir until the powder is dissolved and drink. If you wish you can add fruit juice or fruit syrup immediately before drinking.

Children (below 12 years of age): not recommended.

The recommended dose for faecal impaction is: Adults: The usual dose is 8 sachets a day. The 8 sachets should be taken within a 6-hour period each day for up to 3 days if required. A course of treatment for faecal impaction does not normally exceed 3 days.

If you use Molaxole for treatment of faecal impaction you can mix 8 sachets in one litre of water. The solution can then be stored in the refrigerator.

Patients with impaired cardiovascular function:
For the treatment of faecal impaction, the dose should be divided so that no more than two sachets are taken in any one hour.

Patients with renal insufficiency:
No dosage change is necessary for treatment of either constipation or faecal impaction.

If you take more Molaxole than you should
If you take too much Molaxole and get bad diarrhoea or start vomiting, stop taking Molaxole until it clears, then start again at a lower dose. If you are worried, contact your doctor or pharmacist.

If you forget to take Molaxole
Do not take a double dose to make up for a forgotten dose.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people): Stomach ache and cramp, diarrhoea, vomiting, nausea, stomach rumbles and gastrointestinal gas problems.

Common (may affect up to 1 in 10 people): Itching, headache, swollen hands, feet or ankles.

Uncommon (may affect up to 1 in 100 people): Skin rash, indigestion and bloated stomach.

Very rare (may affect up to 1 in 10,000 people): Serious allergic reactions which cause difficulty in breathing, or swelling of the face, lips, tongue or throat. If any of these symptoms occur, tell your doctor immediately and stop taking Molaxole. Allergic reactions (e.g. skin reaction and runny nose), high and low levels of potassium in the blood and anal discomfort.

Not known (frequency cannot be estimated from the available data): Change in your body's fluid or electrolyte levels (low levels of sodium).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Molaxole

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the sachet and the carton after {Exp.}. The expiry date refers to the last day of that month.

This product does not require any special temperature storage conditions. Store in original package in order to protect from moisture. Ready mixed solution can be stored well covered in refrigerator (2 °C to 8 ° C). Throw away any solution not used within a six-hour period.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Molaxole contains

- The active substances are macrogol 3350 (also known as polyethylene glycol 3350) 13.125 g, sodium chloride 350.7 mg, sodium hydrogen carbonate 178.5 mg, potassium chloride 46.6 mg.
- The other ingredients (excipients) are acesulfame potassium (E950) (sweetener) and lemon flavour (flavouring).

What Molaxole looks like and contents of the pack
White powder for oral solution.
Sachets of 13.8 g in a box of 2, 6, 8, 10, 20, 30, 40, 50, 60 and 100 or 2x50 sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Klocke Pharma-Service GmbH, Strassburger
Strasse 77, D-77767 Appenweier, Germany

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

This medicinal product is authorised in the Member States of the EEA under the following names:

aDenmark:	Moxalole pulver til oral opløsning
Norway:	Moxalole pulver til mikstur, oppløsning
Finland:	Moxalole jauhe oraaliliuosta varten
Hungary:	Moxalole por belsőleges oldathoz
Iceland:	Moxalole 13,125 g/350,7 mg/178,5 mg/46,6 mg mixtúruduft, lausn
Poland:	Duphagol
Sweden:	Moxalole pulver till oral lösning
Austria:	Molaxole - Pulver zur Herstellung einer Lösung zum Einnehmen
Belgium:	Molaxole, poudre pour solution buvable
Bulgaria:	Молаксол® прах за перорален разтвор
Cyprus:	Molaxole κόνις για πόσιμο διάλυμα
Estonia:	Molaxole, suukaudse lahuse pulber
Germany:	Molaxole - Pulver zur Herstellung einer Lösung zum Einnehmen
Ireland:	Molaxole powder for oral solution
Italy:	Molaxole polvere per soluzione orale
Latvia:	Molaxole pulveris iekšķīgi lietojama šķīduma pagatavošanai
Lithuania:	Molaxole milteliai geriamajam tirpalui
Luxembourg:	Molaxole, poudre pour solution buvable
Portugal:	Molaxole pó para solução oral
Romania:	Molaxole pulbere pentru soluţie orală
Slovenia:	Molaxole prašek za peroralno raztopino
Spain:	Molaxole polvo para solución oral EFG
The Netherlands:	Molaxole, poeder voor orale suspensie
United Kingdom:	Molaxole powder for oral solution

This leaflet was last approved in September 2020