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

Read all of this leaflet carefully because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 2 weeks.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor.

In this leaflet:
1. What Molaxole is and what it is used for
2. Before you use Molaxole
3. How to use Molaxole
4. Possible side effects
5. How to store Molaxole
6. Further information

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. Molaxole also works in 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.

2. BEFORE YOU TAKE MOLAXOLE
Do not take Molaxole
- if you are allergic (hypersensitive) to any of the active substances macrogol, sodium chloride, potassium chloride or sodium hydrogen carbonate or any of the other ingredients of Molaxole.
- 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.

Take special care with Molaxole
- if you feel weak, breathless, very thirsty with a headache, have cardiac failure or get puffy ankles 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).

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
If you are pregnant, breast feeding or planning to have a baby, talk to your doctor before you take Molaxole.

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

3. HOW TO TAKE MOLAXOLE
Always take Molaxole exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.

Common 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.

Faecal impaction:
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.

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

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

4. POSSIBLE SIDE EFFECTS
Like all medicines, Molaxole 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MOLAXOLE
Keep out of the reach and sight for children. Do not use Molaxole 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 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 30 sachets.

Manufacturer
Recipharm Höganäs AB, Sporthallsvägen 6, SE-263 34 Höganäs, Sweden
Alternatively
Klocke Pharma-Service GmbH, Strassburger Strasse 77, D-77762 Appenweier, Germany

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