

Package leaflet: Information for the user

Laxaclear 5.9 g, powder for oral solution Macrogol 3350

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

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- If your symptoms of constipation worsen, you must talk to a doctor immediately.
- Talk to a doctor if your symptoms do not improve after 5 days of using Laxaclear.

What is in this leaflet

1. What Laxaclear is and what it is used for
2. What you need to know before you use Laxaclear
3. How to use Laxaclear
4. Possible side effects
5. How to store Laxaclear
6. Contents of the pack and other information

1. What Laxaclear is and what it is used for

Laxaclear contains an ingredient called ‘Macrogol 3350’ (or ‘polyethylene glycol’) and a mixture of salts. It comes as a powder that you dissolve in water to make a drink.

Laxaclear is used as a laxative for short-term relief of constipation. It can be used in adults, adolescents over 12 years of age and the elderly.

Constipation can often be relieved by eating fresh fruit and vegetables, drinking plenty of water and exercising. If these do not work, then Laxaclear can be used.

You must talk to a doctor immediately if your symptoms of constipation worsen.

2. What you need to know before you use Laxaclear

Do not use Laxaclear if:

- you are allergic to Macrogol 3350 (‘polyethylene glycol’) or any of the other ingredients of this medicine (listed in Section 6)
- you have severe inflammatory bowel disease like ‘ulcerative colitis’ or ‘Crohn’s disease’
- you have severe bloating of your gut (‘toxic megacolon’)
- you have a hole or tear in your gut wall
- you have a blockage in your gut (ileus)
- you have ‘phenylketonuria’, a rare inherited condition.

Do not use Laxaclear if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your pharmacist before using Laxaclear if:

- you are on a low sodium diet (for heart failure or high blood pressure)
- you are on a low potassium diet or have kidney problems

If any of the above apply to you (or you are not sure), talk to your pharmacist before using Laxaclear.

Children under 12 years of age

Do not use this medicine in children under 12 years of age.

Other medicines and Laxaclear

Tell your pharmacist if you are using, have recently used or might use any other medicines. Some medicines may not work as effectively during use with Laxaclear.

Laxaclear with food and drink

This medicine can be taken at any time, with or without food or drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think that you might be pregnant or are planning to have a baby, ask your pharmacist for advice before using this medicine.

Driving and using machines

Laxaclear will not affect you being able to drive, cycle or use any tools or machines.

Laxaclear contains sodium, potassium, aspartame and sulphur dioxide

This medicine contains:

- 290 mg sodium (main component of cooking/table salt) in each sachet which is equivalent to 14.5% of the recommended maximum daily dietart intake of sodium for an adult - if you are on a low sodium diet (for heart failure or high blood pressure), you need to take this into account
- 1 mmol (or 40 mg) potassium per sachet which should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet
- 5 mg aspartame (E951) in each sachet. Aspartame is a source of phenylalanine and may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- sulphur dioxide (E220) - may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to use Laxaclear

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

Using this medicine

- Empty the contents of one sachet into a small glass. Add about 100 ml of water to the glass.
- Stir well until all the powder has dissolved. The solution should be clear or slightly cloudy and have a mild vanilla flavour.
- Try and drink the solution straight away. If you cannot drink it straight away, you can keep it at room temperature for up to 2 hours.
- If you use more than one sachet, you must use more water. Use about 100 ml for each sachet.

How much to use

- The usual dose is 1 to 2 sachets each day, taken at the same time.
- Laxaclear usually takes between 24 and 48 hours to start working.
- If the medicine is not working after this time, you can use more sachets. Do not use more than 4 sachets each day.

How long to continue treatment

You should continue using Laxaclear until your constipation is relieved. However, talk to a doctor if symptoms do not improve after 5 days of using Laxaclear.

If you use more Laxaclear than you should

If you use more Laxaclear than you should, this may cause diarrhoea. The diarrhoea will usually stop when you stop using the medicine. If your diarrhoea is severe, talk to your doctor or pharmacist.

If you forget to use Laxaclear

If you forget to use a dose of Laxaclear, use it as soon as you remember.

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

4. Possible side effects

Like all medicines, Laxaclear can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop using Laxaclear and see your doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment

- Serious allergic reaction - the signs may include difficulty breathing or swelling of the face, lips, tongue or throat.

Other side effects

Stomach or gut reactions

- bloating, wind, mild diarrhoea or feeling or being sick
- indigestion, stomach ache or rumbling
- soreness of the anus.

These side effects will usually get better if you reduce the amount of Laxaclear you use.

Mild allergic reactions

- skin reactions such as rash, itching or redness.

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 the national reporting system listed in [Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Laxaclear

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 carton after 'Exp'. The expiry date refers to the last day of that month.

Do not store Laxaclear above 25°C. The mixed Laxaclear solution can be stored at room temperature for up to 2 hours or in the fridge for up to 24 hours.

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

6. Contents of the pack and other information

What Laxaclear contains

- The active ingredient is Macrogol 3350. Each sachet contains 5.9 g Macrogol 3350.
- The other ingredients are Sodium Sulphate Anhydrous, Sodium Chloride, Sodium Hydrogen Carbonate, Potassium Chloride, Aspartame (E951) and Vanilla flavour (containing Caramel Color (E150), Maltodextrin (maize), Gum Arabic/Acacia Gum (E414), Benzyl alcohol and Sulphur Dioxide (E220)).

What Laxaclear looks like and contents of the pack

- Laxaclear is a white or almost white powder to be dissolved in water. The powder dissolves completely to give a clear or slightly cloudy solution with a flavour of vanilla.
- Laxaclear is available as 10 or 20 sachets packed in a box. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Ireland.

Manufacturer

Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Ireland.

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