

Package leaflet: Information for the patient

Laxido Orange, powder for oral solution

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Laxido Orange is and what it is used for

Laxido Orange contains macrogol 3350 and the electrolytes sodium chloride, sodium hydrogen carbonate and potassium chloride.

Macrogol 3350 is a laxative used for the treatment of constipation, especially if you have been constipated for a long time. It is also used to treat a build up of hard faeces in your bowel which may be a result of long-term constipation (this is known as faecal impaction). Macrogol 3350 makes your faeces softer and easier to pass, giving you relief from constipation. The electrolytes help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

2. What you need to know before you take Laxido Orange

Do not take Laxido Orange:

- if you are allergic (hypersensitive) to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients of this medicine (listed in section 6)
- if you have a perforation in the wall of your intestine
- if you have a blockage in your intestine
- if you have paralysis of the intestine (for example, your intestines may stop working due to intestinal surgery or severe infection)
- if you have ulcerative colitis, Crohn's disease or toxic megacolon

If any of these applies to you, please talk to your doctor, pharmacist or nurse for further advice.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Laxido Orange to treat faecal impaction, as prior to taking this medicine it should be confirmed that you have this condition.

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

Other medicines and Laxido Orange

Some medicines, e.g. anti-epileptics, may not work as effectively if they are taken at the same time as Laxido Orange. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not take any other medicines by mouth for one hour before and for one hour after taking Laxido Orange.

If you need to thicken fluids in order to swallow them safely, Laxido Orange may counteract the effect of the thickener.

Laxido Orange with food and drink

Food and drink have no influence on the effect of Laxido Orange.

Pregnancy and breast-feeding

Laxido Orange can be taken during pregnancy and whilst breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Laxido Orange has no effect on the ability to drive or use machines.

Laxido Orange contains potassium and sodium

Laxido Orange contains 0.68mmol (26mg) of potassium per sachet. This should be taken into consideration if you take more than one sachet daily and you have reduced kidney function, or if you are on a controlled potassium diet.

This medicine contains 187mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to approximately 9% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need three or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Laxido Orange

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. Laxido Orange should be taken orally.

Laxido Orange is a laxative for the treatment of constipation and faecal impaction in adults, children (aged 12 years and above) and the elderly.

Constipation

The usual dose for constipation is one sachet taken one to three times daily.

Faecal impaction

The usual dose for faecal impaction is eight sachets daily. All eight sachets must be taken within a six hour period. If you have a heart condition, do not take more than two sachets (in 250ml of water) in any one hour.

How to mix

Laxido Orange should be made up by dissolving the contents of one sachet in a glass of water (125ml or a quarter pint). Stir well until all the powder has dissolved. If you are being treated for faecal impaction, you can dissolve the contents of all eight sachets together in a large container (in one litre of water).

Duration of treatment

Constipation

The course of treatment for constipation does not normally last longer than 2 weeks. Your treatment may last for longer than two weeks if you have ongoing constipation, or a disease that causes constipation (such as Parkinson's disease or multiple sclerosis), or if you are taking other regular medicines that can cause constipation. In these cases, your doctor may reduce your dose to one sachet taken one or two times daily.

Faecal impaction

The course of treatment for faecal impaction does not normally last longer than 3 days.

If you take more Laxido Orange than you should

You may experience severe pains and swelling in your abdomen, or vomiting or diarrhoea, which can lead to dehydration. If this occurs, stop taking Laxido Orange and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Laxido Orange

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Laxido Orange

To get the most benefit from Laxido Orange, always finish the course of treatment recommended by your doctor or pharmacist. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist.

You must contact a doctor if your symptoms worsen or do not improve after 14 days for chronic constipation, or after 3 days for faecal impaction.

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

4. Possible side effects

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

If you experience any of the following side effects, stop taking Laxido Orange and see your doctor immediately:

- signs of a serious allergic reaction, such as difficulty in breathing, or swelling of the face, lips, tongue or throat
- signs of an allergy, such as a rash, reddening of the skin, nettle rash, itching or shortness of breath
- signs of a change in your body's fluid or electrolyte levels, such as swelling (mainly in the ankles), feeling fatigued, dehydration or increased thirst with headache. These symptoms may be a sign that the potassium levels in your blood are higher or lower than normal.

The following side effects are also possible:

- abdominal pain
- feeling bloated
- suffering from wind
- indigestion
- soreness of the anus (bottom)
- mild diarrhoea
- nausea
- vomiting
- swelling of your abdomen
- stomach rumbling

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 Laxido Orange

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 carton and sachet. The expiry date refers to the last day of that month.

You should store unopened sachets below 25°C.

Do not use this medicine if you notice that any of the sachets is damaged.

Reconstituted Laxido Orange solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within six hours. After six hours, any unused solution should be discarded.

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 Laxido Orange contains

The active substances are macrogol 3350 (13.125g), sodium chloride (350.7mg), sodium hydrogen carbonate (178.5mg) and potassium chloride (46.6mg). The other ingredients are acesulfame potassium (E950) and orange flavour (containing maltodextrin and propylene glycol (E1520)).

What Laxido Orange looks like and contents of the pack

Laxido Orange is a white powder that is packed in sachets. It has an orange taste and smell.

Each sachet contains 13.8g of powder and is packed in cartons containing 2, 8, 10, 20, 30, 50 and 100 sachets. Not all of these pack sizes are marketed.

Marketing Authorisation Holder

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Co Louth
Ireland

Manufacturer

Almac Pharma Services Limited
Almac House
20 Seagoe Industrial Estate
Craigavon
BT63 5QD
UK

Almac Pharma Services (Ireland) Limited
Finnabair Industrial Estate
Dundalk
Co Louth
A91 P9KD
Ireland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Germany, Spain, Ireland, Luxembourg and United Kingdom (Northern Ireland) –
Laxido Orange
Finland – Laxido Appelsiini
Portugal – Laxido Laranja
Sweden – Laxido Apelsin
Italy - Laxido

This leaflet was last revised in September 2021.

Laxido is a trade mark