

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lacrofarm, powder for oral solution, sachet

Text to be used nationally where Lacrofarm is available without prescription:

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms worsen or do not improve after 14 days for constipation.

Text to be used nationally where Lacrofarm is subject to medical prescription:

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 further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. 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 Lacrofarm is and what it is used for
2. What you need to know before you take Lacrofarm
3. How to take Lacrofarm
4. Possible side effects
5. How to store Lacrofarm
6. Contents of the pack and other information

1. What Lacrofarm is and what it is used for

The name of this medicine is Lacrofarm

- It is a laxative for the treatment of **chronic** constipation in adults, children (aged 12 years and above) and the elderly.
- It helps you to have a comfortable bowel movement even if you have been constipated for a long time. It also works in very bad constipation called faecal impaction (complete severe constipation).

2. What you need to know before you take Lacrofarm

Do not take Lacrofarm

- if you are allergic 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 perforated gut wall.
- if you have a blockage in your intestine (gut obstruction, ileus) for example by paralysis of the intestine.

- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

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

Warnings and precautions

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

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

Other medicines and Lacrofarm

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 together with Lacrofarm and for one hour before and for one hour after taking Lacrofarm.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Lacrofarm.

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

Pregnancy and breast-feeding

Lacrofarm can be used during pregnancy or while 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

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

Lacrofarm contains sodium

This medicine contains 187 mg sodium (main component of cooking/table salt) per sachet.

This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 3 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 Lacrofarm

For medicines available without prescription:

Always take Lacrofarm 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.

For medicines available on prescription only:

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

Chronic Constipation (constipation for a long time)

Dosage – adults and children above 12 years

1 sachet one to three times daily. The 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 of treatment contact your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take Lacrofarm for longer than 2 weeks. If you need to take Lacrofarm for longer, please see your doctor.

Children (below 12 years of age)

Not recommended.

Patients with a heart condition

Do not take more than 2 sachets in one hour.

Faecal Impaction (complete severe constipation)

Before you take this medicine for faecal impaction, it should be confirmed by a doctor that you have this condition.

Dosage – adults and children above 12 years

The usual dose for faecal impaction (complete severe constipation) is 8 sachets daily. The 8 sachets should be taken within a 6 hour period each day for up to 3 days if required.

Children (below 12 years of age)

Not recommended.

Patients with a heart condition

Do not take more than 2 sachets in one hour.

How to use Lacrofarm

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

Dissolve the contents of 1 sachet in a glass of water (125ml or ¼ pint), stir well and drink. If you are being treated for faecal impaction it may be easier to dissolve all 8 sachets in 1 litre of water.

If you take more Lacrofarm than you should

You may develop diarrhoea, which can lead to dehydration. If this occurs, stop taking Lacrofarm and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Lacrofarm

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

4. Possible side effects

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

Tell your doctor immediately and stop taking Lacrofarm if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and may have mild diarrhoea when starting to take Lacrofarm. These side effects generally get better if you reduce the amount Lacrofarm you take.

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 Lacrofarm

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

Do not use Lacrofarm after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

Once you have made up Lacrofarm in water, if you cannot drink it straight away keep it covered and store in a refrigerator (2°C – 8°C). Throw away any solution not used within a 24 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 Lacrofarm 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 ingredient is acesulfame potassium (E950) as a sweetener.

What Lacrofarm looks like and contents of the pack

Lacrofarm is a white powder packed in sachets.

It is available in boxes of 2, 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

OTC packages: [To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last approved in 2023-10-27.