

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lacrofarm Junior, powder for oral solution, sachet

Read all of this leaflet carefully before you give this medicine to your child 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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 Junior is and what it is used for
2. What you need to know before you give Lacrofarm Junior
3. How to use Lacrofarm Junior
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1. What Lacrofarm Junior is and what it is used for

The name of this medicine is Lacrofarm Junior. It is a laxative for the treatment of chronic constipation in children aged 1 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

It helps your child to have a comfortable bowel movement even if they have been constipated for a long time.

2. What you need to know before you give Lacrofarm Junior

Do not give Lacrofarm Junior if your doctor has told you that your child has:

- an allergy to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients of this medicine (listed in section 6).
- a perforated gut wall.
- a blockage in their intestine (gut obstruction, ileus)
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

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

If your child has a heart or kidney problem, an impaired gag reflex or reflux oesophagitis (heart-burn caused by back-flow of stomach contents into the oesophagus), you should talk to your doctor before giving Lacrofarm Junior.

If your child 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 giving your child Lacrofarm Junior and contact your doctor immediately. The symptoms have been seen in treatment of adults.

Other medicines and Lacrofarm Junior

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

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

When taking large volumes of Lacrofarm Junior (e.g. for faecal impaction), other medicines may be flushed through your digestive system. Your child should not take any other medicines by mouth together with Lacrofarm Junior and for one hour before and for one hour after taking Lacrofarm Junior.

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

Pregnancy and breast-feeding

Lacrofarm Junior can be used during pregnancy or while breast-feeding. Talk to your doctor or pharmacist before giving Lacrofarm Junior.

Driving and using machines

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

Lacrofarm Junior contains sodium

This medicine contains 93 mg (4.06 mmol) sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Lacrofarm Junior

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

Chronic Constipation:

The dose of Lacrofarm Junior depends on the age of the child and their response to treatment.

- As a starting dose, children aged 1 to 6 years should be given 1 sachet each day.
- Children aged 7 to 11 years should be given 2 sachets each day.

Your doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement. If the dose does need increasing, this should be done every other day. For children below 2 years of age, no more than 2 sachets should be taken in one day. For children 2 to 11 years, normally, no more than 4 sachets are required to be taken in one day.

It is not necessary to take all of the drink at one time, if the child prefers it, half the drink can be taken in the morning and half in the evening.

Faecal Impaction:

Before your child takes Lacrofarm Junior for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment for faecal impaction in children aged 5 to 11 years is as follows:

Number of Lacrofarm Junior sachets							
Age (years)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5 - 11	4	6	8	10	12	12	12

The daily number of sachets should be taken in divided doses, all consumed within 12 hours (e.g. 8am to 8pm). Each sachet dissolved in 62.5 ml (1/4 of a glass) of water. Treatment can be stopped when the medicine has worked. This is shown by the child passing large volumes of stool and/or watery diarrhoea.

How to use Lacrofarm Junior

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

- Open the sachet and pour the contents into a glass. Add ¼ glass (about 62.5ml) of water to the glass. Stir well until all the powder has dissolved.
- If you like you can add a flavour such as orange squash to the drink.
- If your child is taking Lacrofarm Junior for faecal impaction it may be easier to dissolve 12 sachets in 750ml of water.

Duration of Treatment

- Chronic constipation: Treatment needs to be for a prolonged period of time, at least 6-12 months.
- Faecal impaction: Treatment can be for up to 7 days.

If your child takes more Lacrofarm Junior than they should

Your child may develop excessive diarrhoea. If this occurs, stop giving Lacrofarm Junior and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Lacrofarm Junior

Give 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 Junior can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop giving Lacrofarm Junior if your child:

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

Very common side effects (may affect more than 1 in 10 people):

- stomach pains
- stomach rumbles.

Common side effects (may affect up to 1 in 10 people):

- diarrhoea
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom).

If your child is being treated for **chronic constipation**, diarrhoea will usually improve when the dose is reduced.

Uncommon side effects (may affect up to 1 in 100 people):

- swollen stomach
- wind.

Rare side effects (may affect up to 1 in 1000 people):

- allergic reactions, which may include breathlessness or difficulty in breathing.

Other side effects reported include:

Skin rash (hives), itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches, indigestion, high or low levels of potassium in the blood.

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 Junior

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

Do not use Lacrofarm Junior 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 Junior in water, if your child cannot drink it straight away keep it covered and in the fridge (2 – 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 Junior contains

The active substances are macrogol 3350 (6.563g), sodium chloride (175.4mg), sodium hydrogen carbonate (89.3mg) and potassium chloride (23.3mg).

The other ingredient is acesulfame potassium (E950) as a sweetener.

When it is made into a drink with 62.5 ml ($\frac{1}{4}$ glass) of water, each sachet gives the equivalent of:

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen carbonate	17 mmol/l
Potassium	5.4 mmol/l

What Lacrofarm Junior looks like and contents of the pack

Lacrofarm Junior 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.

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.