Package leaflet: Information for the user

Lactulose Sandoz 670 mg/ml, strooplactulose

lactulose

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 or pharmacist have 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. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after several days.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] belongs to a group of medicines known as laxatives. Lactulose, the active substance, makes the stool softer and easier to pass by drawing water into the bowel. It is not absorbed into your body.

[Nationally completed name] is used to treat
- Symptoms of **constipation**

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- if you are allergic to lactulose.
- if you suffer from
  - galactosaemia (a severe genetic disorder where you cannot digest galactose).
  - blockage in your gastrointestinal tract (apart from normal constipation).
  - digestive perforation or a risk of digestive perforation (e.g. acute inflammatory bowel disease such as Crohn's disease or ulcerative colitis).

Warnings and precautions
Talk to your doctor before taking [Nationally completed name] if you suffer from any medical conditions or illnesses, in particular:
- if you suffer from unexplained tummy ache.
- if you do not feel better or if you feel worse after several days.

- if you suffer from gastro-cardiac syndrome (Roemheld syndrome). A syndrome where accumulation of gas in the gastrointestinal tract or disturbances in the normal flow of stomach contents trigger/cause cardiac symptoms.
- if you are unable to digest milk sugar (lactose).
- if you have diabetes.

You should not take [Nationally completed name] if you suffer from:
- Galactose or fructose intolerance
- Lapp lactase deficiency
- Glucose-galactose malabsorption

For patients with Roemheld syndrome: If you have symptoms like meteorism or bloating after taking [Nationally completed name], stop the treatment and consult your doctor. In these cases your doctor will supervise the treatment carefully.

Long-term use of unadjusted dosages - exceeding 2-3 soft stools per day - or misuse, can lead to diarrhoea and disturbance of the mineral balance (see section 3 Duration of use).

Elderly patients, or those in bad general condition taking [Nationally completed name] longer than 6 months, require regular blood checks of their mineral levels.

Children
[Nationally completed name] should only be given to children under doctor's supervision. In special circumstances your doctor may prescribe [Nationally completed name] for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. [Nationally completed name] should only be given to infants and smaller children if indicated as it can influence the normal reflexes for passing stools.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

The following medicines can affect or be affected by [Nationally completed name]:
- **medicines to increase urine output** with active substance names mostly ending with "thiazide" or "tizide"
- **medicines to treat inflammation** or prevent organ transplant rejection, such as cortisone
- **amphotericin B**: a medicine to treat fungal infections
- **medicines to treat heart weakness**, such as digitoxin, digoxin

Pregnancy, breast-feeding and fertility
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.

[Nationally completed name] may be used during pregnancy and breast-feeding.
No effects on fertility are to be expected.

Driving and using machines
[Nationally completed name] has no or negligible influence on the ability to drive and use machines.

[Nationally completed name] contains milk sugar (lactose), galactose or fructose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor

before taking this medicine.

3. How to take [Nationally completed name]

Always take this medicine 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.

The recommended dose is:

	Starting dose (per day)		Maintenance dose (per day)	
Adults and adolescents over 14 years	15-45 ml	corresponding to 10-30 g lactulose	15-30 ml	corresponding to 10-20 g lactulose
Children 7-14 years	15 ml	corresponding to 10 g lactulose	10-15 ml	corresponding to 7-10 g lactulose
Children 1-6 years	5-10 ml	corresponding to 3-7 g lactulose	5-10 ml	corresponding to 3-7 g lactulose
Infants under 1 year	up to 5 ml	corresponding to up to 3 g lactulose	up to 5 ml	corresponding to up to 3 g lactulose

If diarrhoea occurs, the dose should be reduced.

Children
Use of laxatives in children and infants should be exceptional and under medical supervision because it can influence the normal reflexes for passing stools.
Please do not give [Nationally completed name] to children under the age of 14 years before consulting your doctor for prescription and careful supervision.

Elderly patients and patients with renal or hepatic insufficiency
In elderly patients and patients with reduced kidney or liver function no special dosage recommendations exist.

Method of use
You can take [Nationally completed name] undiluted or diluted in some liquid, with or without food.
Use the measuring cup provided.
Swallow the medicine quickly. Do not keep it in your mouth.
The daily dose should be taken all at once in the morning, or divided into two doses per day.
Drink at least 1.5 to 2 litres of liquid per day during treatment with laxatives.

Duration of use
The daily dose can be taken for 2-3 days until the desired effect has been achieved.
Please do not use [Nationally completed name] without medical advice for more than two weeks (see section 2).

If you take more [Nationally completed name] than you should
Please contact your doctor or pharmacist.

When you have taken too much [Nationally completed name], diarrhoea and abdominal pain may occur.

If you forget to take [Nationally completed name]
If you have forgotten to take a dose, then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Nationally completed name]
The desired effect of the medicine may not be achieved.

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

4. Possible side effects

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

Side effects can occur with the following frequencies:

Very common, may affect more than 1 in 10 people
- diarrhoea

Common, may affect up to 1 in 10 people
- flatulence (wind)
- nausea (feeling sick)
- vomiting
- abdominal pain

Uncommon, may affect up to 1 in 100 people
- electrolyte imbalance due to diarrhoea

Not known, (frequency cannot be estimated from the available data)
- Allergic reactions, rash, itching, hives.

Flatulence may occur during the first few days of treatment. As a rule it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 [Nationally completed name]

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 label of the bottle as well on the outer carton after "EXP". The expiry date refers to the last day of that month.
Do not store above 25°C.

After first opening [Nationally completed name] can be used for 1 year.

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 [Nationally completed name] contains
The active substance is lactulose (as lactulose liquid).
One ml of [Nationally completed name] solution contains 670 mg lactulose.

There are no other ingredients.

What [Nationally completed name] looks like and contents of the pack
[Nationally completed name] is a clear, viscous liquid, colourless or pale brownish-yellow solution and is available in following packsizes:

NL/H/2325/001
Brown PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 100ml, 10 x 100 ml, 200ml, 250 ml, 300ml, 500 ml, 1000 ml
White PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 100 ml, 200 ml, 300 ml, 500 ml, 1000 ml
Brown glass bottles with polyethylene screw cap containing 100ml, 200ml, 250 ml, 300ml, 500 ml, 1000 ml

NL/H/2354/001
Brown PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 180ml and 200ml.

As measuring device a measuring cup (polypropylene) with filling marks at 5, 10, 15, 20, 25 and 30 ml is added

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Manufacturers
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

LEK S.A.
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02-672 Warschau

Polen

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Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

MA-number:
RVG 109595

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

Nederland	Lactulose Sandoz 670 mg/ml, stroop
Italië	Lattulosio Sandoz GmbH

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024