PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactulose Fresenius 670 mg/ml oral solution
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 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. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Lactulose Fresenius is and what it is used for

Lactulose Fresenius contains a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

Lactulose Fresenius is used to:

- treat the symptoms of constipation
- treat a special liver disease (portal systemic encephalopathy)

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Lactulose Fresenius

Do not take Lactulose Fresenius

- if you are allergic to lactulose or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from
    - galactosaemia (a severe genetic disorder where you cannot digest galactose)
    - acute inflammatory bowel disease (like Crohn's disease or ulcerative colitis) blockage in your bowel (apart from normal constipation), digestive perforation or risk of digestive perforation, abdominal pain of undetermined cause

Warnings and precautions
Talk to your doctor or pharmacist before taking Lactulose Fresenius.
Please tell your doctor before taking Lactulose Fresenius if you suffer from gastro-cardiac syndrome (Roemheld syndrome).

If you have symptoms like meteorism or bloating after using it, stop the treatment and consult your doctor.
In these cases your doctor will supervise the treatment carefully.

Longterm use of unadjusted dosages (exceeding 2 - 3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolytes balance.
If you are an elderly patient or a patient in bad general condition and take lactulose for a more than 6 months period, your doctor will regularly check your blood electrolytes

Patients with portal systemic encephalopathy should avoid concomitant administration of other laxatives, because it hinders the individualization of drug dose.
Please do not use Lactulose Fresenius without medical advice for more than two weeks.

From the route of synthesis Lactulose "Fresenius" may contain traces of sugars.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 l/day, equal to 6 - 8 glasses).

Children
Lactulose Fresenius should not normally be given to infants and smaller children as it can disturb the normal reflexes for passing stools.
In special circumstances your doctor may prescribe Lactulose Fresenius for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.

Other medicines and Lactulose Fresenius
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Lactulose may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphothericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.
With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.

Lactulose Fresenius with food and drink
Lactulose Fresenius can be taken with or without food. There are no restrictions on what you can eat or drink.

Pregnancy and 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
Lactulose Fresenius will not affect your ability to drive safely or use machines.

Lactulose Fresenius contains milk sugar (lactose), galactose or epilactose.
Please refer to section ”Warnings and precautions".

15 ml of Lactulose contain 42.7 KJ (10.2 kcals) = 0.21 bu. The dose used for treatment may need to be taken into considerations for diabetics.

3. How to take Lactulose Fresenius

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.

Take your doses at the same time each day. The dose may be given once daily, for example during breakfast, or divided up to three doses a day.
Swallow the medicine quickly. Do not keep it in your mouth.

You can take Lactulose Fresenius oral solution undiluted or diluted in some liquid. Use the measuring cup provided.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 l/day, equal to 6 - 8 glasses).

The recommended dose is:

For Constipation:

	Starting dose		Maintenance dose	
Adults	15 - 45 ml	corresponding to 10 - 30 g lactulose	15 - 30 ml	corresponding to 10 - 20 g lactulose

Use in children and adolescents

	Starting dose		Maintenance dose	
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		
Babies	up to 5 ml	corresponding to up to 3 g lactulose		

Thereafter the dose can be reduced individually.
The daily dose should be taken at once during the breakfast. It can be take 2 - 3 days until the desired effect will be achieved since lactulose is not degraded until it reaches the colon.

For Portal systemic encephalopathy (Malfunction of the brain resulting from a liver disease)

Beginning with 30 - 50 ml 3 times daily (corresponding to 60 - 100 g Lactulose).
The dosage has to be adopted to get 2 - 3 soft stools daily, pH of the stools should be between 5.0 to 5.5.

In elderly patients and patients with renal or hepatic insufficiency no special dosage recommendations exist.

Use in children and adolescents
The safety and efficacy in children aged 0 - 18 years has not been established.

If you take more Lactulose Fresenius than you should
In case of overdosage, you may experience diarrhoea and abdominal pain. Contact your doctor or pharmacy if you have taken more Lactulose Fresenius than you should.

If you forget to take Lactulose Fresenius
If you forgot to take Lactulose Fresenius just 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 Lactulose Fresenius
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.
The following side effects have been reported with Lactulose Fresenius:

Very common (may affect more than 1 in 10 people):
- Flatulence (wind), especially during the first few days of treatment. This usually disappears after a couple of days
- When a higher dose than recommended is used, you may experience abdominal pain. In such a case the dosage should be decreased.

Common (may affect up to 1 in 10 people):
- Nausea (feeling sick)
- Vomiting
- When a higher dose than recommended is used, you may experience diarrhoea (sometimes including electrolyte imbalance). In such a case the dosage should be decreased.

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

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lactulose Fresenius

Do not store above 25°C.

Keep container tightly closed.

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 and / or on the outer carton after "exp". The expiry date refers to the last day of that month.

After first opening Lactulose Fresenius 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 to protect the environment.

6. Contents of the pack and other information

What Lactulose Fresenius contains

- The active substance is Lactulose (as lactulose liquid).
  One ml of Lactulose Fresenius solution contains 670 mg lactulose.
- There are no other ingredients

What Lactulose Fresenius looks like and contents of the pack

Lactulose Fresenius is a clear, viscous liquid, colourless or pale brownish-yellow solution and is available in following packsizes:
Brownglass- and brown PET-bottles containing 100 ml, 200 ml, 250 ml, 300 ml, 500 ml and 1000 ml, 10 x (100 ml, 200 ml, 250 ml, 300 ml, 500 ml) and 6 x 1000 ml with a polyethylene screw cap or a polypropylene child resistant closure. White PET-bottles: containing 100 ml, 200 ml, 300 ml, 500 ml and 1000 ml, 10 x (100 ml, 200 ml, 300 ml, 500 ml) and 6 x 1000 ml with a polyethylene screw cap or a polypropylene child resistant closure.
As measuring device a measuring cup (polypropylene) with filling marks is added.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Fresenius Kabi Austria GmbH
Hafnerstraße 36
8055 Graz, Austria

Manufacturer
Fresenius Kabi Austria GmbH
Estermannstraße 17
4020 Linz, Austria

For any information about this medicine, please contact the local representative of the Marketing Authorizsation Holder:

Rowex Ltd, Newtown
Bantry, Co Cork
Tel: +353 (0) 27-50077
Fax: +353 (0) 27-50417

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

Austria:	Lactulose Hexal 670 mg/ml - Lösung zum Einnehmen
Czech Republic:	Laktulosa Sandoz 670 mg/ml
France:	Lactulose Fresenius 670 mg/ml, solution buvable en flacon
Ireland:	Lactulose Fresenius 670 mg/ml oral solution
Latvia:	Lactulose Fresenius 670 mg/ml šķīdums iekšķīgai lietošanai
Germany:	Lactulose Fresenius 670 mg/ml Lösung zum Einnehmen
Netherlands:	Lactulose Fresenius 670 mg/ml, stroop
Sweden:	Lactulose Fresenius 670 mg/ml - Oral lösning
United Kingdom:	Lactulose 670 mg/ml Oral solution

This leaflet was last revised in April2018