

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactulose 10g/15 ml Oral Solution Sachets
Lactulose

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Lactulose carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT LACTULOSE IS AND WHAT IT IS USED FOR

Lactulose 10 g/15 ml oral solution sachets 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 is used to treat the symptoms of constipation.

2. BEFORE YOU TAKE LACTULOSE

Do not take Lactulose if you:

- are allergic (hypersensitive) to any of the components of Lactulose
- suffer from galactosaemia (a severe genetic disorder where you cannot digest galactose), acute inflammatory bowel disease (such as Crohn's disease or ulcerative colitis), blockage in your bowel (apart from normal constipation), digestive perforation or risk of such perforation or unexplained abdominal pain

Take special care with Lactulose
Please tell your doctor before taking Lactulose if you suffer from gastro-cardiac syndrome (Roemheld syndrome).
If you have symptoms like excess gas in your bowels 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 who take lactulose for a more than 6 months period, your doctor will regularly check your blood electrolytes.

Please do not use Lactulose without medical advice for more than two weeks.
During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 litres per day, equal to 6-8 glasses).

Children up to 6 years:
Lactulose 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 for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.

Taking other medicines
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription.

Lactulose may increase the loss of potassium caused by other drugs (e.g. thiazides, steroids and amphotericin B). Use of cardiac glycosides (e.g. digoxin) along with Lactulose can increase the effect of the glycosides by decreasing potassium in the blood. 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.

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

Pregnancy and breast-feeding
Talk to your doctor before you use Lactulose if you are pregnant or breast-feeding.

Driving and using machines
Lactulose will not affect your ability to drive safely or use machines.

Important information about some of the ingredients of Lactulose

Lactulose may contain small amounts of sugars (lactose, galactose or epilactose).
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
May contain more than 5 g lactose/galactose/epilactose depending upon the dose taken.
This should be taken into account in patients with diabetes mellitus.

15 ml of Lactulose contain 42.7 KJ (10.2 kcal) = 0.21 BU.

3. HOW TO TAKE LACTULOSE

Always take Lactulose exactly as described in this leaflet .You should 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 into two or three doses a day.
Swallow the medicine quickly. Do not keep it in your mouth.

You can take Lactulose oral solution undiluted or diluted in some liquid.

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

For a precise dosing for babies, toddlers and children up to 6 years, it should be noted that not all included dose recommendations can be carried out with Lactulose and that other authorised products are available.

Constipation:				
	Starting dose		Maintenance dose	
Adults and adolescents over 14 years	15-45ml daily	1-3 sachets, corresponding to 10-30 g lactulose	15-30ml daily	1-2 sachets, corresponding to 10-20 g lactulose
Children (7-14 years)	15ml daily	1 sachet, corresponding to 10 g lactulose	15ml daily	1 sachet, corresponding to 10 g lactulose

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

Children:
Please do not give Lactulose to children before consulting your doctor for prescription and careful supervision.

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

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

If you forget to take Lactulose
If you forget to take a dose of Lactulose, do not worry. Just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

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

If you stop taking Lactulose

The desired effect of the medicine may not be achieved.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lactulose can cause side effects, although not everybody gets them. The frequencies are defined as follows:

very common: affects more than 1 user in 10
common: affects 1 to 10 users in 100
uncommon: affects 1 to 10 users in 1,000
rare: affects 1 to 10 users in 10,000
very rare: affects less than 1 user in 10,000
not known: frequency cannot be estimated from the available data

The following side effects have been reported with Lactulose:

Very common:

- 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.

Common:

- Nausea (feeling sick)
- Vomiting
- When a higher dose than recommended is used, you may experience diarrhoea.

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.

For patients in the United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For patients in Ireland

You can also report side effects directly via e-mail to imbpharmacovigilance@imb.ie. Alternatively you can call +353 1 6764971.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LACTULOSE

Do not store above 25°C.

Keep out of the sight and reach of children.

Do not use Lactulose after the expiry date which is stated on the outer carton and sachets after "exp". The expiry date refers to the last day of that month.

Partially used sachets have to be discarded.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lactulose contains

- The active substance is Lactulose (as lactulose liquid)
- One sachet (15 ml) of Lactulose oral solution contains 10 g lactulose.
- There are no other ingredients

What Lactulose looks like and contents of the pack

Lactulose 10 g/15 ml oral solution is a clear, viscous liquid, colourless or pale brownish-yellow solution and is available in following pack sizes: 10, 20, 30, 50 and 100 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder UK and Ireland

Fresenius Kabi Austria GmbH
Hafnerstraße 36
8055 Graz, Austria

Manufacturer

Fresenius Kabi Austria GmbH
Estermannstraße 17
4020 Linz, Austria

Distributor in the United Kingdom and Ireland:

Intrapharm Laboratories Limited
The Courtyard Barns,
Choke Lane,
Cookham Dean,
Maidenhead,
Berks SL6 6PT.
United Kingdom

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

Austria:	Laevolac 10g/15ml - Lösung zum Einnehmen
Czech Republic:	Laktulosa Sandoz sáčky 10g/15ml
Estonia:	Franirose
Ireland:	Lactulose 10g/15ml Oral Solution Sachets
Latvia:	Franirose 10g/15ml šķīdums iekšķīgai lietošanai
Lithuania:	Lactulose Sandoz 10g/15ml geriamasis tirpalas
Germany:	Lactulose unterwegs - 1 A Pharma 66,7g/100ml Lösung zum Einnehmen
Netherlands:	Laevolac 10g/15ml - stroop
Norway:	Lactulose Fresenius Kabi
Romania:	Lactuloză Sandoz 10g/15ml soluție orală
Spain:	Lactulosa Sandoz 10g solución oral eb sobres EFG
Sweden:	Lactulose Fresenius 10g oral lösning, dospåse
United Kingdom:	Lactulose 10g/15ml oral solution sachets; Laevolac 10g/15ml - Oral solution

This leaflet was last revised in September 2013.