FRESENIUS KABI

**Package Leaflet 160 x 520 mm**

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**1st Side**

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Lactulose 10 g/15 ml Oral Solution Sachets
## 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 3 days.

**What is in this leaflet**


### 1. WHAT LACTULOSE IS AND WHAT IT IS USED FOR

Lactulose 10 g/15 ml oral solution sachets contain 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 indicated in adults and in children and adolescents aged 7 to 18 years.
For children below 7 years, other dosage forms are available.
Lactulose is used to treat the symptoms of constipation.

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

**Do not take Lactulose:**
- 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 or unexplained abdominal pain.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking 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.

Long-term use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolyte 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.

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

**Children and adolescents**
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.

**Other medicines and Lactulose**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

Lactulose may increase the loss of potassium caused by other drugs (e.g. thiazides, steroids and amphothericin 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.

**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, 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.

**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.
Lactulose 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 kcals) = 0.21 BU.

### 3. HOW TO TAKE LACTULOSE

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 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).

It can take 2-3 days until the desired effect has been achieved since Lactulose is not degraded until it reaches the colon.

The recommended dose is:

| | Starting dose | | Maintenance dose | |
|---|---|---|---|---|
| Adults | 15-45 ml daily | 1-3 sachets, corresponding to 10-30 g lactulose | 15-30 ml daily | 1-2 sachets, corresponding to 10-20 g lactulose |

Thereafter the dose can be reduced individually.

In elderly patients and patients with kidney or liver disease no special dosage recommendations exist.



**Reverse**

**Use in children and adolescents**
Please do not give Lactulose to children before consulting your doctor for prescription and careful supervision.

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

Thereafter the dose can be reduced individually.
For a precise dosing for infants, toddlers and children up to 6 years, lactulose is available in bottles.

**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 medicine, 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 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:
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.

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).

**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:

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 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

Do not store above 25 °C.

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 outer carton and sachets after "EXP". The expiry date refers to the last day of that month.

Partially used sachets have to be discarded.

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 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 the following pack sizes:
10, 20, 30, 50 and 100 sachets.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**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:**

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|---|---|
| Austria: | Laevolac 10 g/15 ml - Lösung zum Einnehmen |
| Ireland: | Lactulose 10 g/15 ml Oral Solution Sachets |
| Netherlands: | Laevolac 10 g/15 ml - stroop |
| Norway: | Lactulose Fresenius Kabi |
| Romania: | Lactuloză Sandoz 10 g/15 ml soluție orală |
| Spain: | Lactulosa Sandoz 10 g solución oral en sobres EFG |
| Sweden: | Lactulose Fresenius 10 g oral lösning, dospåse |
| United Kingdom: | Lactulose 10 g/15 ml oral solution sachets; Laevolac 10 g/15 ml - Oral solution |

**This leaflet was last revised in 05/2015.**