

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Lactulose 3.3g/5ml Oral Solution

#### Lactulose

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

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

#### **What is in this leaflet**

1. What Lactulose oral solution is and what it is used for
2. What you need to know before you take Lactulose oral solution
3. How to take Lactulose oral solution
4. Possible side effects
5. How to store Lactulose oral solution
6. Contents of the pack and other information

### **1. WHAT LACTULOSE ORAL SOLUTION IS AND WHAT IT IS USED FOR**

Lactulose oral solution 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.

#### **Lactulose oral solution is used to treat**

- Symptoms of **constipation**

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LACTULOSE ORAL SOLUTION**

#### **Do not take Lactulose oral solution**

- if you are allergic to Lactulose oral solution or any of the other ingredients of this medicine (listed in section 6)
- if you have any blockage in your bowel that is not due to constipation
- if you have a stomach or bowel perforation or a risk of this
- if you have abdominal pain of undetermined cause
- if you cannot digest galactose due a genetic disorder called galactosaemia

#### **Warnings and precautions**

Talk to your doctor before taking Lactulose oral solution if you have heart problems caused by much gas in bowel or stomach, called Roemheld syndrome. Your doctor will supervise the treatment carefully in this case. Stop treatment and consult your doctor if you have symptoms like wind or bloating after using Lactulose oral solution.

Drink at least 1.5 to 2 litres of liquid per day during treatment with laxatives.

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.

Elderly patients, or those in bad general condition taking Lactulose oral solution longer than 6 months, require regular blood checks of their mineral levels.

### Children and adolescents

Lactulose oral solution should only be given to children under doctor's supervision.

### Other medicines and Lactulose oral solution

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 Lactulose oral solution:

- **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
- **mesalazine**, a medicine to treat disease with long-lasting bowel inflammation

### 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.

Lactulose oral solution may be used during pregnancy and breast-feeding.

### Driving and using machines

Lactulose oral solution has no influence on the ability to drive and use machines.

### Lactulose oral solution contains certain sugars

Lactulose oral solution may contain milk sugar (lactose), galactose or fructose. 15 ml of Lactulose oral solution contains 42.7 KJ (10.2 kcals) = 0.21 bu. This should be taken into account in patients with diabetes mellitus.

## 3. HOW TO TAKE LACTULOSE ORAL SOLUTION

Always take this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

### Constipation

	Starting dose (per day)		Maintenance dose (per day)	
Adults and adolescents over	15-45 ml	corresponding to 10-30 g	15-30 ml	corresponding to 10-20 g

14 years		lactulose		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
Babies 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

The daily dose should be taken all at once in the morning, or divided into two doses per day. It can be taken for 2-3 days until the desired effect has been achieved.

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

### Method of use

You can take Lactulose oral solution 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.

### Duration of use

Please do not use Lactulose oral solution without medical advice for more than two weeks.

### If you take more Lactulose oral solution than you should

Please contact your doctor or pharmacist.

When you have taken too much Lactulose oral solution, diarrhoea and abdominal pain may occur.

### If you forget to take Lactulose oral solution

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 Lactulose oral solution

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, 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 per 10 users

- wind, especially during the first few days of treatment  
This usually disappears after a couple of days
- abdominal pain

**Common**, may affect up to 1 in 10 users

- nausea

- vomiting
- diarrhoea, if the dose is too high

**Not known**, (frequency cannot be estimated from the available data)

- Allergic reactions, rash, itching, hives.

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

## 5. HOW TO STORE LACTULOSE ORAL SOLUTION

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 label of the bottle as well on the outer carton after "EXP". The expiry date refers to the last day of that month.

After first opening Lactulose oral solution 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 Lactulose oral solution contains

The active substance is lactulose as lactulose liquid.

One ml of Lactulose oral solution contains 670 mg lactulose.

There are no other ingredients.

### What Lactulose oral solution looks like and contents of the pack

Lactulose oral solution is a clear, viscous liquid, colourless or pale brownish-yellow solution and is available in following pack sizes:

Brown PET bottles with polyethylene screw cap or polypropylene closure containing 100ml, 10 x 100 ml, 200ml, 250 ml, 300ml, 500 ml, 1000 ml

White PET bottles with polyethylene screw cap or 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

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 Limited  
Park View, Riverside Way  
Watchmoor Park  
Camberley, Surrey  
GU15 3YL  
United Kingdom

**Manufacturer**

Lek Pharmaceuticals d.d.  
Verovškova 57,  
1526 Ljubljana  
Slovenia

LEK S.A.  
ul. Domaniewska 50 C,  
02-672 Warszawa  
Poland

Salutas Pharma GmbH  
Otto-von-Guericke-Allee 1,  
39179 Barleben  
Germany

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