PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactulose 3.3 g/5 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 ORAL SOLUTION IS AND WHAT IT IS USED FOR

Lactulose oral solution contains the active substance lactulose. Lactulose is a laxative and it makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body and reaches the colon unchanged.

Lactulose oral solution 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 ORAL SOLUTION

Do not take Lactulose oral solution:
- 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.
Please tell your doctor before taking Lactulose oral solution 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 oral solution for more than a 6 month 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 oral solution without medical advice for more than two weeks.

From the route of synthesis Lactulose oral solution 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 oral solution 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 oral solution for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.

Other medicines and Lactulose Oral Solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Lactulose oral solution 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 oral solution with food and drink
Lactulose oral solution 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 oral solution will not affect your ability to drive safely or use machines.

Lactulose oral solution contains milk sugar (lactose), galactose, epilactose, tagatose or fructose.
Please refer to section "Warnings and precautions".

15 ml of Lactulose oral solution 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 ORAL SOLUTION

Always take Lactulose oral solution 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 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 once during breakfast. It can be taken for 2-3 days until the desired effect is achieved since Lactulose oral solution is not degraded until it reaches the colon.

For portal systemic encephalopathy (Liver disease that affects the brain)

Adults:
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.

Use 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 oral solution 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 oral solution than you should.

If you forget to take Lactulose oral solution
If you forget to take a dose of Lactulose oral solution, 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 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 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 oral solution:

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 and diarrhoe.

Common (may affect up to 1 in 10 people):
- Nausea (feeling sick)
- Vomiting

Not known (frequency cannot be estimated from the available data):
- Allergic reactions
- Rash
- Itching
- Hives

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.

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 Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LACTULOSE ORAL SOLUTION

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 (EXP: mm yyyy). The expiry date refers to the last day of that month.

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 oral solution contains

- The active substance is Lactulose (as lactulose liquid).
  5 ml of Lactulose oral solution contains 3.3 g 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 glass, PET bottles or HDPE bottles containing 200 ml, 300 ml, 500 ml and 1000 ml.

A measuring cup (polypropylene) with filling marks is added as measuring device.
Not all pack sizes may be marketed.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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