

Package leaflet: Information for the user

Lactulose solution

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, pharmacist or nurse 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, pharmacist or nurse. 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 you feel worse after 2-3 days.

What is in this leaflet:

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

1. What Lactulose is and what it is used for

- Lactulose belongs to a group of medicines called osmotic laxatives, which help to retain water in the bowels and soften the stools. Lactulose solution encourages normal bowel action.
- Lactulose is used to:
 - relieve constipation
 - treat the brain disturbance associated with liver disease known as hepatic encephalopathy including unconsciousness caused by liver problems.

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)
- are lactose intolerant (because this medicine contains lactose)
- suffer from galactosaemia (which results in an accumulation of galactose-1-phosphate and /or galactose in the blood) or require a galactose-free diet (because this medicine contains galactose)
- suffer from gastro-intestinal obstruction (a blockage of the gut).

Warnings and precautions

Talk to your doctor before taking Lactulose if you:

- have diabetes. Lactulose contains the sugar, lactose. In normal doses, this should not affect your blood sugar levels
- have taken Lactulose for several days and you do not feel it is working properly, please tell your doctor.

Other medicines and Lactulose

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Pregnancy and breast-feeding

- Lactulose should be used with caution during the first 3 months of pregnancy.
- 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 can be used during pregnancy if necessary.

- Lactulose can be used when breast-feeding if necessary.

Driving and using machines

Lactulose is not known to affect your ability to drive or operate machinery.

Lactulose contains galactose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Lactulose

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.

If your symptoms persist after taking this medicine, consult your doctor.

The solution should be swallowed with a drink of water, fruit juice or taken with a meal.

Always use the measuring cup supplied with the pack. Rinse the measuring cup with water after use.

The recommended dose is:

Constipation

- **Adults:** 15 ml twice daily
- **Children 5-10 years:** 10 ml twice daily
- **Children 1-5 years:** 5 ml twice daily
- **Babies under 1 year:** 2.5 ml twice daily.

Hepatic Encephalopathy

- **Adults including the elderly**
30 to 50 ml three times a day, which should then be adjusted to a daily dosage which produces 2 - 3 soft stools each day.

It may be two or three days before the full benefit of treatment is obtained. After this time, you may be able to reduce the dose you take according to your needs.

If you take more Lactulose than you should

If you (or someone else) swallow a lot of the solution all together, or if you think a child has accidentally swallowed any of the solution contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining solution, and the container with you to the hospital or doctor so that they know which solution has been consumed. You may have loose stools and abdominal pain.

If you forget to take Lactulose

If you forget to take the solution, take it as soon as you remember, unless it is nearly time to take the next dose. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Lactulose

If your doctor has prescribed this medicine, you should take it for as long as the doctor has instructed.

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.

If the following happens, stop taking the solution and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

- cramps
- increased wind and feeling bloated. This may happen during the first few days of treatment. These effects usually disappear after a few days
- abdominal pain, being sick
- loose stools. This may happen if you take high doses of Lactulose. If this happens, lower your dose. If you have loose stools, drink plenty of fluids to prevent dehydration. High doses may make you feel sick, which can be minimised by taking Lactulose solution with water, fruit juice or with a meal.

These effects are often mild and usually wear off after a few days of treatment. If they are severe or last for more than a few days, tell your doctor.

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 the Yellow Card Scheme at 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

Keep out of the sight and reach of children. Do not store above 25°C. Do not freeze. Do not use this medicine after the expiry date that is stated on the outer packaging. 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 solution contains:

- The active ingredient is lactulose.
- The other ingredients are lactose and galactose.

What Lactulose solution looks like and contents of the pack:

- Lactulose solution contains 3.35 g of lactulose per 5 ml.
- The product is available in pack sizes of 100, 150, 200, 300, 500, 1000, 2500 and 5000 ml solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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CE logo + 0473

The CE mark only covers the measuring cup.

Manufacturer of the measuring cup: TEVA UK Limited, Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX

Note this will need to be on the front face of the folded label/leaflet