

PACKAGE LEAFLET: INFORMATION FOR THE USER
Lactulose 3.3g/5ml Oral Solution

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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs illness are the same as yours.
- If any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

The name of your medicine is Lactulose Solution, it belongs to a group of medicines called laxatives. It is used in:

- Constipation - constipation is a common complaint often due to not enough roughage or fibre in the diet, dehydration, immobility, illness or stress. Sometimes constipation may be due to more serious reasons. Lactulose can help the bowel move, and pass a stool if you are constipated. It acts by drawing water into the bowel and softening the stool or motion. In this way, Lactulose can encourage a normal bowel motion.
- Advanced liver disease marked by a disturbance of mental functioning (Hepatic encephalopathy).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LACTULOSE SOLUTION

Do not take Lactulose Solution if you:

- Are allergic (hypersensitive) to Lactulose, Galactose, Lactose, Epilactose, Tagatose and Fructose (See section 6).
- Suffer from a rare inherited condition of the metabolism, called galactosaemia (an increase in a sugar called galactose in the blood).
- Are suffering from a blockage in your gut or intestine.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Lactulose Solution:

- If you are diabetic

Other Medicines and Lactulose Solution

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

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:

There should be no problems when taking Lactulose solution.

Lactulose solution contains Lactose, Galactose and Fructose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE LACTULOSE SOLUTION

Lactulose Solution is for oral use only.

Lactulose solution may be taken with a drink such as water or juice.

To treat constipation

The details mentioned below give the starting dose of Lactulose solution depending on your age. However, the dose may be adjusted by your doctor depending on your needs to have the desired effect.

Adults, the elderly and children over 12 years:

15 ml twice daily (3 x 5ml spoonfuls), gradually reduced.

Children 5 to 12 years:

10 ml twice daily (2 x 5ml spoonfuls), gradually reduced.

Children 1 to 5 years: 5 ml (1 x 5ml spoonful)

Babies under 1 year: 2.5ml (½ x 5ml spoonful)

To treat Hepatic Encephalopathy

Higher doses of Lactulose are required. Starting dose is 30 to 50 ml three times daily. (6-10 x 5ml spoonfuls), then adjusted to produce 2 or 3 soft stools daily.

If you take more Lactulose Solution than you should

If you take more Lactulose Solution than you should, contact your doctor or nearest hospital emergency department immediately. Take any remaining solution with you so that the staff know exactly what you have taken.

If you forget to take Lactulose Solution

If you forget to take a dose of Lactulose solution, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten one.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lactulose solution can cause side effects, although not everybody gets them. If any of these side effects become troublesome, stop taking the medicine and see your doctor as soon as possible.

If **the** following happens, stop using this medicine and tell your doctor immediately or go to the nearest hospital emergency department.

- allergic reactions such as difficulty of breathing, swelling of your face, lips, throat or tongue, skin rash, itching and hives.

Other side effects:

- Gas
- bloated stomach
- stomach cramps
- stomach or intestine discomfort.

If you are taking large doses of Lactulose solution to treat hepatic encephalopathy, you may also suffer from feeling sick (nausea), vomiting (being sick), diarrhea, low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm. In such a case, please tell your doctor as he can adjust your dose to obtain two to three stools a day.

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 the leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LACTULOSE SOLUTION

Keep all medicines out of the sight and reach of children.

Store below 25°C.

Store in a cool dry place.

Do not use Lactulose solution after the expiry date on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via the waste-water or household waste. Ask your pharmacist how to dispose of medicine which is no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lactulose Solution contains

5 ml of Lactulose Solution contains 3.3g of Lactulose. May also contain Galactose, Lactose, Epilactose, Tagatose and Fructose.

What Lactulose Solution looks like and contents of the pack

Lactulose solution is a clear viscous liquid, colourless or pale brownish-yellow.

Lactulose solution is available in 200ml, 300ml, 500ml & 1000ml plastic bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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