

Package leaflet: Information for the patient

Lactulose 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. 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

- Lactulose Solution contains 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.

What Lactulose Solution is used for

- Lactulose Solution is used to treat constipation (infrequent bowel movements, hard and dry stools).
- Lactulose Solution is used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). This is also known as a 'hepatic coma'.
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2. What you need to know before you take Lactulose Solution

Do not take Lactulose Solution if:

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of Lactulose Solution (listed in Section 6).
- You have a rare problem called 'galactosaemia'.
- You have an intestinal blockage caused by anything else but normal constipation, digestive perforation or risk of digestive perforation.

Do not take Lactulose Solution if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lactulose Solution.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Lactulose Solution if you suffer from any medical conditions or illnesses, in particular:

- if you suffer from unexplained stomach pains
- if you are unable to digest lactose (sugar found in milk)
- if you have diabetes

You should not take Lactulose Solution if you suffer from:

- galactose or fructose intolerance
- glucose-galactose malabsorption
- Lapp lactase deficiency

If you have diabetes and are treated for hepatic encephalopathy, your dose of Lactulose Solution will be higher. This high dose contains a large amount of sugar. Therefore, your anti-diabetic medicine may need to be adjusted.

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

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

If you take Lactulose Solution for several days and there is no improvement in your condition or if your symptoms worsen, please contact your doctor.

Paediatric population

In special circumstances your doctor may prescribe Lactulose Solution for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. Lactulose Solution should only be given to infants and smaller children if indicated as it can influence the normal reflexes for passing stools.

Other medicines and Lactulose Solution

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

Taking Lactulose Solution with food and drink

Lactulose Solution can be taken with or without food. There are no restrictions on what you can eat or drink.

Pregnancy, breast-feeding and fertility

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Lactulose Solution can be used during pregnancy and when breast-feeding if necessary. No effects on fertility are to be expected.

Driving and using machines

Lactulose Solution has no or negligible influence on your ability to drive safely or use machines.

Important Information about some of the Ingredients of Lactulose Solution

Lactulose Solution may contain small amounts of milk sugar (lactose), galactose, epilactose or fructose. 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 Solution

Always take Lactulose Solution 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.

Taking this medicine

- Take Lactulose Solution from a spoon.
- You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 6-8 glasses throughout the day)
- Swallow the dose immediately. Do not keep it in your mouth as the sugar content may lead to tooth decay, particularly if Lactulose Solution is taken for long periods.
- Lactulose Solution takes 2 to 3 days to start working.
- After this time you may be able to reduce the dose you take according to your needs.

Constipation

Adults and adolescents: The starting dose is 15-45ml per day. After this the dose can be adjusted to 15-30ml daily.

Children 7 to 14 years: The starting dose is 15ml. After this the dose can be adjusted to 10-15ml daily.

Children 1 to 6 years: The usual dose is 5-10ml daily.

Infants under 1 year: The usual dose is up to 5ml daily.

Use in Children: Use of laxatives in children, infants, and babies should be exceptional and under medical supervision because it can influence the normal reflexes for passing stools. Please do not give Lactulose Solution to children (under 14 years) before consulting your doctor for prescription and careful supervision.

Hepatic encephalopathy (adults only)

Adults: The usual starting dose is 3 to 4 times a day of 30-45ml.

Use in Children: No information is available for treatment of children (newborn to 18 years of age) with hepatic encephalopathy.

Use in elderly patients and patients with renal or hepatic insufficiency: No special dosage recommendations exist.

If you take more Lactulose Solution: than you should

If you take more Lactulose Solution than you should stop taking Lactulose Solution and talk to a doctor or pharmacist. You may have diarrhoea, loss of electrolytes and abdominal pain.

If you forget to take Lactulose Solution

If you forget a dose of Lactulose 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 Solution

Do not stop or change the treatment before talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lactulose Solution can cause side effects, although not everybody gets them. The following side effects have been reported with Lactulose Solution:

Very common (may affect more than 1 in 10 people)

- diarrhoea

Common (may affect up to 1 in 10 people)

- flatulence (wind)
- nausea (feeling sick)
- vomiting
- abdominal pain

Uncommon (may affect up to 1 in 100 people)

- electrolyte imbalance due to diarrhoea

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

- Allergic reactions (hypersensitivity)
- Rash
- Itchiness/itchy skin
- Hives

Flatulence may occur during the first few days of treatment. As a rule it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

If you use high doses (normally only associated with hepatic encephalopathy, HE) for an extended period of time, you may experience an electrolyte imbalance due to diarrhoea.

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 **United Kingdom** 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 Solution

Keep this medicine out of the reach and sight of children.

Do not use Lactulose Solution after the expiry date which is stated on the carton or bottle.

The expiry date refers to the last day of that month

Do not store above 25°C. Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information**What Lactulose Solution contains**

- The active substance in Lactulose Solution is lactulose. Each 5ml of Lactulose Solution contains 3.35g of lactulose.
- Lactulose Solution does not contain any other ingredients. However, it may contain small amounts of other sugars, such as lactose, galactose, epilactose and fructose.

What Lactulose Solution looks like and contents of the pack

- Lactulose Solution is a clear, viscous liquid, colourless to brownish yellow liquid.

Lactulose solution is available in:

- Amber glass bottles with screwcaps of 200 ml, 300 ml, and 500 ml.

- Plastic bottles with screwcaps of 200 ml, 300 ml, 500 ml, 1000 ml and 5000 ml.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Kent Pharma UK Limited, 2nd Floor, Connect 38,
1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release: Fannin (UK) Limited, 42-46 Booth Drive,
Park Farm South, Wellingborough, NN8 6GT, UK

This information is available in alternative formats upon request.

This leaflet was last revised in February 2026