

LACTULOSE SOLUTION

3.35g/5ml

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 if you feel worse after several days.

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 is a laxative. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

It is used to treat:

- constipation (infrequent bowel movements, hard and dry stools)
- hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). This is also known as a 'hepatic coma'.

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 (listed in Section 6)
- you have a rare problem called 'galactosaemia'
- you have a 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 tummy ache
- if you are unable to digest milk sugar (lactose intolerant)
- if you have diabetes.

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, you may need to adjust the dose of your anti-diabetic medicine.

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

Children

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.

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.

Lactulose Solution contains lactose, galactose and fructose

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

Project		Date 25/05/2017		Proof 1	
Market Trade Name	Lactulose Oral 3.35g/5ml	Print Colours	1		Non-Print
Item Number	P0573T				
Market or Pack Owner	Crescent Pharma Ltd.				
Dimensions	210 x 297mm - Leaflet	Technical Colours			
Font Size	10 pt				
Pharmacode	205				
Quality Assurance		Regulatory Affairs		Marketing	
Approval Date:		Approval Date:		Approval Date:	
Observations:		Observations:		Observations:	
<p>Please Note! We cannot accept responsibility for any errors in this proof after approval. Whilst we take extreme care at all times to ensure accuracy to our client's brief, the final responsibility must be taken by our client.</p> <p>IF YOU SIGN THIS PROOF YOU ARE SIGNIFYING FULL APPROVAL OF DESIGN AND TEXT.</p>					

Taking this medicine

Take this medicine from a spoon or measuring cup. 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 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. Lactulose may be taken either as a single daily dose or in 2 divided doses; if taken as a single daily dose then this should be at the same time each day, for example during breakfast.

Constipation

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

Children 7 to 14 years: The starting dose is 15ml daily. 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 30 - 45ml 3 to 4 times a day.

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 and talk to a doctor or pharmacist. You may have diarrhoea 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 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:

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.

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, 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. 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 sight and reach of children.

Do not use this medicine 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.

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 Solution contains

The active ingredient 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, colourless to brownish yellow, viscous liquid. It is available in plastic bottles containing 300ml or 500ml. Not all pack sizes may be marketed.

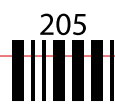
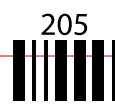
Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hampshire, RG25 3ED, UK.

Manufacturer: Crescent Manufacturing Limited, 2 Cunard Road, Park Royal, London, NW10 6PN, UK.

This leaflet was last revised in May 2017

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Project		Date 27/04/2017		Proof 5	
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Item Number	P0520T				
Market or Pack Owner	Crescent Pharma Ltd.				
Dimensions	210 x 297mm - Leaflet	Technical Colours			
Font Size	10 pt				
Pharmacode	205				
Quality Assurance		Regulatory Affairs		Marketing	
Approval Date:		Approval Date:		Approval Date:	
Observations:		Observations:		Observations:	
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