

Package leaflet: Information for the patient

**Lactulose 3.335 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 have 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 your doctor if you do not feel better or if you feel worse after several days.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine

6. Contents of the pack and other information

1. What this medicine is and what it is used for
This medicine 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.

Lactulose is used to treat constipation (infrequent bowel movements, hard and dry stools). Lactulose is also used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). Hepatic encephalopathy can lead to a hepatic coma.

2. What you need to know before you take this medicine

Do not take this medicine if:

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of this medicine (listed in section 6)
- You have a rare problem called 'galactosaemia' (a severe genetic disorder where you cannot digest galactose)
- You have a blockage caused by anything else but normal constipation, digestive perforation or risk of digestive perforation.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine 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

You should not take this medicine if you suffer from:

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

If you have diabetes and are treated for hepatic encephalopathy, your dose of lactulose 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 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 this medicine for several days (2 to 3 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 this medicine for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. This medicine 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

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

Lactulose with food and drink

Lactulose 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. This medicine can be used during pregnancy and when breast-feeding

if necessary.

No effects on fertility are to be expected.

Driving and using machines

This medicine has no or negligible influence on your ability to drive safely or use machines.

Important information regarding the ingredients of this medicine

This medicine may contain small amounts of milk sugar (lactose), tagatose, galactose, epilactose or fructose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take this medicine

Always take this medicine exactly described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 this medicine is taken for long periods.
- This medicine 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 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.

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 this medicine 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 impairment: No special dosage recommendations exist.
If you take more of this medicine than you should
 If you take more of this medicine than you should stop taking Lactulose and talk to a doctor or

pharmacist straight away.
 You may have diarrhoea, loss of electrolytes and abdominal pain.
If you forget to take this medicine
 If you forget to take a dose do not worry. Just take your next dose at the usual time.
 Do not take a double dose to make up for a forgotten dose.
If you stop taking this medicine
 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 with Lactulose:
Very common (may affect more than 1 in 10 people)
 • diarrhoea
Common (may affect up to 1 to 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly as below:
In UK: 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.
In Ireland: via the HPRA website: www.hpra.ie or email to: medsafety@hpra.ie. V. By reporting side effects you can help provide more information on the

safety of this medicine.
5. How to store this medicine
 • Keep this medicine out of the sight and reach of children.
 • Store below 25°C. Use within 12 months of first opening
 • Do not use this medicine after the expiry date which is stated on the label after EXP. 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 protect the environment.
6. Contents of the pack and other information
What this medicine contains
 • The active substance is lactulose. Each 5ml of oral solution contains 3.335g of lactulose.
 • This medicine does not contain any other ingredients.
 However, it may contain small amounts of other sugars such as lactose, galactose, epilactose, tagatose and fructose.
What this medicine looks like and contents of

the pack
 • This medicine is clear, viscous liquid, colourless or pale brownish yellow.
 • This medicine is available in bottles of 100ml, 200ml, 300ml, 500ml and 1000 ml. A measuring cup with filling marks is supplied with each container. Not all pack sizes may be marketed.
Marketing Authorisation Holder
 Bristol Laboratories Ltd.,
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 Telephone: 0044 (0)1442 200922

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Dosage: For oral use. Read the package leaflet before use.
CONSTIPATION
Adults and adolescents: Initially 15-45 ml (3-9x5ml spoonfuls) twice daily. **Children 7 to 14 years:** Initially 15 ml (3x5ml spoonful) daily. 5-10 years – 10ml (2x5ml spoonfuls) twice daily.
 The above dosage serves as a guide. Dosage may vary depending on the condition. Eventually the dosage should be adjusted, usually reduced to meet the needs of the individual. Do not exceed the stated dose.
Children 1 to 6 years: Usually 5-10 ml (1-2 ml spoonfuls) daily.
Infants under 1 year: Usually 5 ml (1 spoonful) daily.
HEPATIC ENCEPHALOPATHY (Adults only): Initially 30-45 ml (6-9x5 ml spoonfuls) 3 to 4 times daily. Adjust dose to produce 2 or 3 soft stools daily.
Storage: Keep out of the sight and reach of children. Store below 25°C. Use within 12 months of first opening.



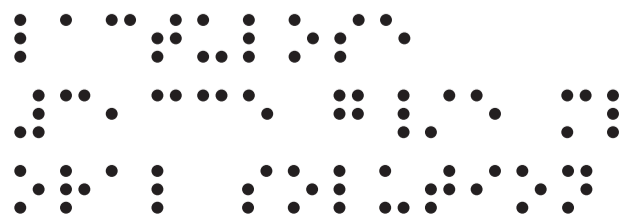
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 MA Holder:
 Bristol Laboratories Ltd.,
 Berkhamsted, Herts, HP4 1EG, UK
 BN:
 EXP:

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V8 25-09-19 D0

Ph. Code

Lactulose
 3.335 g/5 ml
 oral solution



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