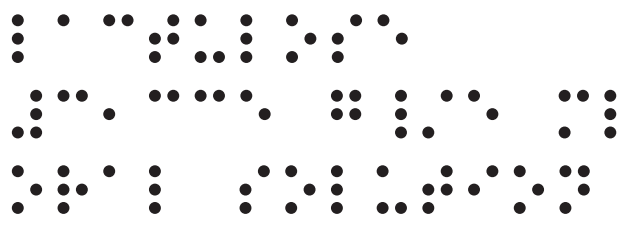


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Lactulose
3.335 g/5 ml
oral solution



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Marketing Authorisation Holder

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Lactulose 3.335 g/5 ml oral solution; PL 17907/0534

This leaflet was last revised in May 2022.

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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.

Lactulose

oral solution

3.335 g/
5 ml

500 ml

Relieves Constipation

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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

- What this medicine is and what it is used for
- What you need to know before you take this medicine

- 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.

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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.

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

- Allergic reactions, rash, itching, hives.

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 the 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 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.

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)

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- 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
- total 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

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.

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