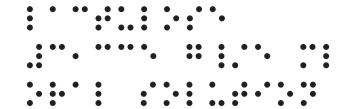
# Braille to be embossed

Lactulose 3.335 g/5 ml oral solution



### Marketing Authorisation Holder

Bristol Laboratories Ltd., Unit 3, Canalside, Northbridge Road, Berkhamsted,

Hertfordshire, United Kingdom, HP4 1EG Telephone: 0044 (0)1442 200922 0044(0)1442 873717 info@bristol-labs.co.uk

Manufacturer Pharmadan A/S, Sognevej 92, DK-9620 Aalestrup,

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

This leaflet was last revised in May 2022.

To request a copy of this leaflet in braille, large print or audio format, please contact the licence holder at the address (or telephone, fax,

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 spoonfus) 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.

500 ml Lactulose 3,335 g/ oral solution 5 ml ✓ Relieves Constipation

• Ingredients: Each 5 ml of oral solution contains 3.335 g of lactulose. Also contains small amounts of lactose, galactose, tagatose, epilactose and fructose. See leaflet for further information.

148 mm

page 12

150 mm

page 1

#### Package leaf let: Information for the patient

Lactulose 3.335 g/5 ml oral solution

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.
- 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.
- 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.

150 mm

page 2

148 mm

page 11

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

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 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)

148 mm

page 10

148 mm page 3

50 mm

You have a blockage caused by anything else but normal constipation, digestive perforation or risk of digestive

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

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:

- total lactase deficiency
- galactose or fructose intolerance

- 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

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.

148 mm

148 mm

Hepatic encephalopathy (adults only) amount of sugar. Therefore, you may need to adjust the dose of your anti-diabetic medicine Adults: The usual starting dose is 3 to 4 times a day of 30-45ml. Chronic use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the 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 During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 litres/day, equal to 6-8 glasses). If you take more of this medicine than you should 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, 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 In special circumstances your doctor may prescribe this medicine for a child, infant or baby. In these cases your doctor will supervise If you forget to take a dose, do not worry. Just take your next dose at the usual time. the treatment carefully. This medicine should only be given to infants and smaller children if indicated as it can influence the normal Do not take a double dose to make up for a forgotten dose. reflexes for passing stools If you stop taking this medicine Other medicines and Lactulose Do not stop or change the treatment before talking to your doctor. Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. If you have any further questions on the use of this medicine, ask your doctor or pharmacist. Lactulose with food and drink Lactulose can be taken with or without food. There are no restrictions on what you can eat or drink 148 mm 148 mm

page 8 page 5

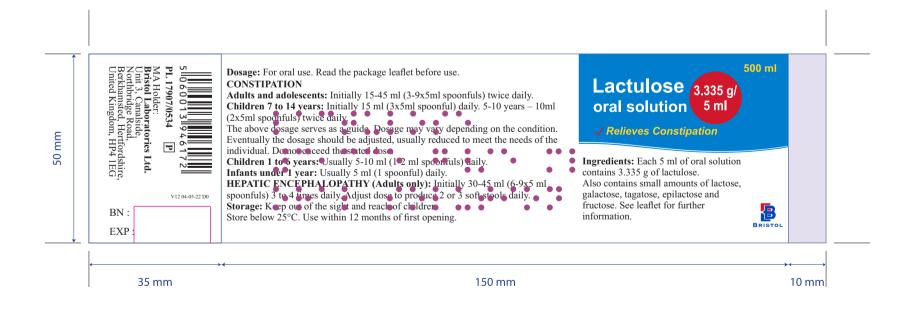
You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 6-8 glasses Pregnancy, breast-feeding and fertility Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. This throughout the day) Swallow the dose immediately. Do not keep it in your mouth as the sugar content may lead to tooth decay, particularly if medicine can be used during pregnancy and when breast-feeding if necessary. this medicine is taken for long periods. No effects on fertility are to be expected. 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. Driving and using machines This medicine has no or negligible influence on your ability to drive safely or use machines. Constipation 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 medicinal product. 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. 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 148 mm 148 mm

page 6 page 7

# Times New Roman 7.5 pt



Times New Roman 7.5 pt

Lactulose 3.335 g/5 ml oral solution

