

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### 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. 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 Lactulose is and what it is used for
2. What you need to know before you take Lactulose
3. How to take Lactulose
4. Possible side effects
5. How to store Lactulose
6. Contents of the pack and other information

## **1. What Lactulose is and what it is used for**

#### **What Lactulose is**

- Lactulose 3.335 g/5 ml oral 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 is used for**

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

## **2. What you need to know before you take Lactulose**

#### **Do not take Lactulose if:**

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of Lactulose (see sections 2 and 6).
- You have a rare problem called 'galactosaemia'.
- You have a blockage caused by anything else but normal constipation, gastrointestinal perforation or risk of perforation.

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

#### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Lactulose 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 Lactulose 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 amount of sugar. Therefore, your doctor may recommend that you 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 Lactulose 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 for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. Lactulose 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, have recently taken or might take any other medicines.

### **Taking 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. Lactulose can be used during pregnancy and when breast-feeding if necessary.

No effects on fertility are to be expected.

### **Driving and using machines**

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

### **Important Information about some of the Ingredients of Lactulose**

Lactulose contains sugars, such as milk sugar (lactose), galactose 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.

Lactulose contains sulphite.

## **3. How to take Lactulose**

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

### **Taking this medicine**

- Take Lactulose 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 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.

### **Constipation**

**Adults and adolescents:** The starting dose is 15-45ml or 1-3 sachets per day. After this the dose can be adjusted to 15-30ml or 1-2 sachets daily.

**Children 7 to 14 years:** The starting dose is 15ml or 1 sachet daily. After this the dose can be adjusted to 10-15ml or 1 sachet daily.

**Children 1-6 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 to children (under 14 years) before consulting your doctor for prescription and careful supervision.

### **Hepatic encephalopathy**

**Adults:** The usual starting dose is 3 to 4 times a day of 30-45ml or 2-3 sachets.

**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 than you should**

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

### **If you forget to take Lactulose**

If you forget a dose of Lactulose, 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**

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 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 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, rash, itching, 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. By reporting side effects you can help provide more information on the safety of this medicine. You can also report side effects directly via the MHRA Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **5. How to store Lactulose**

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

Do not use Lactulose 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 contains**

- The active substance in Lactulose 3.335 g/5 ml oral solution is lactulose. Each 5ml of Lactulose contains 3.335g of lactulose.
- Lactulose does not contain any excipients.
- Lactulose contains residues from the route of production, see section 2.

### **What Lactulose looks like and contents of the pack**

- Lactulose is a clear, viscous liquid, colourless to brownish-yellow liquid.
- Lactulose is available in 15 ml sachets and in plastic bottles containing 200ml, 300ml, 500ml and 1000ml.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK.

#### **Manufacturer**

Abbott Biologicals B.V., 8121 AA, Olst, The Netherlands.

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**Braille text:** Lactulose 3.335 g/5 ml oral solution