PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactulose 10 g/15 ml Oral Solution Sachets

Read this leaflet carefully before you start using this medicine because it contains important information about your treatment.

Always keep this leaflet and the blister pack until you have finished your treatment. 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.

1. WHAT LACTULOSE IS AND WHAT IT IS USED FOR

Lactulose is an osmotic laxative, containing a neutral sugar called lactulose. It makes the stools softer and makes passage easier. By drawing water into the bowel it is not absorbed into your body. Lactulose is indicated in adults and children aged 6 or more years.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LACTULOSE

Before you start treatment with Lactulose:

- If you have had abdominal surgery, or have had bowel (apart from normal constipation), digestive perforation or risk of digestive perforation or acute inflammatory bowel disease (like Crohn’s disease or ulcerative colitis), blockage in your bowel or bowel obstruction, talk to your doctor before taking this medicinal product.
- If you suffer from galactosaemia (a severe genetic disorder where you cannot digest galactose), contact your doctor before taking this medicinal product.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- If you have kidney or liver disease, contact your doctor before taking this medicinal product.
- If you are taking any of the following medicine, talk to your doctor before taking Lactulose.
  - Diuretics (such as an aldosterone antagonist), because this could increase the risk of an electrolyte imbalance (e.g. potassium). Use of cardiac glycosides (e.g. digoxin) along with Lactulose can increase the risk of an electrocardiographic abnormality (primarily prolongation of the Q-T interval), but this is not of clinical significance. Use of cardiac glycosides (e.g. digoxin) along with Lactulose can increase the risk of an electrocardiographic abnormality (primarily prolongation of the Q-T interval), but this is not of clinical significance.
  - Lactulose may cause diabetes mellitus.
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  - If you are pregnant or breast-feeding talk to your doctor or pharmacist before taking this medicine.

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.

3. HOW TO TAKE LACTULOSE

Take your doses at the same time each day. Do not take more Lactulose than you should. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Very common (may affect more than 1 in 10 people):
- Flatulence (wind), especially during the first few days of treatment. This usually disappears after a couple of days.
- Very common (may affect more than 1 in 10 people):
  - Abdominal pain.
  - Vomiting

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

In special circumstances your doctor may prescribe Lactulose for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.

5. HOW TO STORE LACTULOSE

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

Use in children and adolescents

<table>
<thead>
<tr>
<th>Age</th>
<th>Starting dose</th>
<th>Maintenance dose</th>
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</thead>
<tbody>
<tr>
<td>7-14 years</td>
<td>1 sachet</td>
<td>1 sachet</td>
</tr>
<tr>
<td>15-18 years</td>
<td>2 sachets</td>
<td>2 sachets</td>
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</tbody>
</table>

Thereafter the dose can be reduced individually in elderly patients and patients with kidney or liver disease so special dosage recommendations are not necessary.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lactulose contains
- Lactulose is an osmotic laxative (Lactulose solution).
- One sachet (10 ml) of Lactulose oral solution contains 10 g lactulose.
- There are no other ingredients.

What Lactulose looks like and contents of the pack
Lactulose is supplied as a clear viscous liquid in 10, 20, 30, 50 and 100 sachets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Fresenius Kabi Austria GmbH
Hafnerstraße 36
A-1040 Vienna, Austria

Manufacturer
Estermannstraße 17
40514 Suhl, Germany

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