FRONT

Package leaflet: Information for the user

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.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Lactulose 3.335 g/5 ml Oral Solution is and what it is used for
2. What you need to know before you take Lactulose 3.335 g/5 ml Oral Solution
3. How to take Lactulose 3.335 g/5 ml Oral Solution
4. Possible side effects
5. How to store Lactulose 3.335 g/5 ml Oral Solution
6. Contents of the pack and other information

1. What Lactulose 3.335 g/5 ml Oral Solution is and what it is used for

The name of this medicine is Lactulose 3.335 g/5 ml Oral Solution. It 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 3.335 g/5 ml Oral Solution is used to treat constipation (infrequent bowel movements, hard and dry stools). It is used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, and decreased level of consciousness). Hepatic encephalopathy can lead to a hepatic coma.

2. What you need to know before you take Lactulose 3.335 g/5 ml Oral Solution

Do not take Lactulose 3.335 g/5 ml Oral Solution if:
- You are allergic to lactulose or any of the other ingredients of this medicine (listed in section 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 3.335 g/5 ml Oral Solution if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Pharmacode

Warnings and precautions
Talk to your doctor or pharmacist before taking Lactulose 3.335 g/5 ml Oral Solution 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 3.335 g/5 ml Oral Solution if you suffer from:
- galactose or fructose intolerance
- total lactase deficiency
- glucose-galactose malabsorption (condition in which the body cannot absorb the sugars glucose and galactose)

If you have diabetes and are treated for hepatic encephalopathy, your dose of Lactulose 3.335 g/5 ml Oral Solution 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 (approximately 2 liters per day, equal to 6-8 glasses).

If you take this medicine for several days and there is no improvement in your condition or if your symptoms worsen, contact your doctor.

Children
In special circumstances your doctor may prescribe Lactulose 3.335 g/5 ml Oral Solution 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 3.335 g/5 ml Oral Solution
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Lactulose 3.335 g/5 ml Oral Solution 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.

Lactulose 3.335 g/5 ml Oral Solution contains lactose, galactose and fructose
This medicine contains sugars, such as milk sugar (lactose), galactose and fructose.
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Lactulose 3.335 g/5 ml Oral Solution contains sulphite
May rarely cause severe hypersensitivity reactions and bronchospasm

3. How to take Lactulose 3.335 g/5 ml Oral Solution

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

BACK

Taking this medicine
- Take Lactulose 3.335 g/5 ml Oral Solution from a 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).
- You can take this medicine with or without food.
- 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.
- Lactulose 3.335 g/5 ml Oral Solution 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 over 14 years: Starting dose: 15-45 ml for the first 2 to 3 days of treatment. Maintenance dose: 15-30 ml daily as required, or as directed by your doctor.
Children (7 to 14 years): Starting dose: 15 ml for the first 2 to 3 days of treatment. Maintenance dose: 10-15 ml as required, or as directed by your doctor.
Children (1-6 years): 5-10 ml daily as required, or as directed by your doctor.
Infants under 1 year: Up to 5 ml daily as required, or as directed by your doctor.

Hepatic Encephalopathy:
Adults: Beginning with 30 - 45 ml, 3 to 4 times a day. The dosage has to be adopted to get two or three soft stools daily.
Children: Not recommended

In elderly patients and patients with renal or hepatic insufficiency no special dosage recommendations exist.

If you take more Lactulose 3.335 g/5 ml Oral Solution than you should
If you take more medicine than you should stop taking Lactulose 3.335 g/5 ml Oral Solution and talk to a doctor or pharmacist. You may have diarrhoea, loss of electrolytes and abdominal pain.

If you forget to take Lactulose 3.335 g/5 ml Oral Solution
If you forget a dose of this medicine, 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 3.335 g/5 ml Oral Solution
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 3.335 g/5 ml Oral Solution:
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 (being sick)
- 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 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 Lactulose 3.335 g/5 ml Oral Solution

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the bottle and carton. This expiry date refers to the last day of that month. Do not use after 90 days of first opening of the bottle.
Do not store above 25°C. Do not refrigerate or freeze.
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 Lactulose 3.335 g/5 ml Oral Solution contains
Each 5 ml of Lactulose 3.335 g/5 ml Oral Solution contains 3.335 g of lactulose. It does not contain any excipients.
Lactulose contains residues from the route of production, see section 2.

What Lactulose 3.335 g/5 ml Oral Solution looks like and contents of the pack
Lactulose is a clear, viscous liquid, colorless to pale brownish-yellow.
Lactulose 3.335 g/5 ml Oral Solution is available in round amber PET bottles containing 200, 300 and 500 ml.
Each carton contains one bottle and a 30 ml graduated measuring cup with intermediate graduations of 5 ml. Not all pack sizes may be marketed.

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