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lactugal®
Lactulose Solution
Liquid medicine for the relief of constipation and for the treatment of hepatic encephalopathy.
For oral administration
Banana Flavour.
500 ml
PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactugal®
Lactulose Solution 500 ml

Read all of this label 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 doctor pharmacist if you need more information or advice.
• You must contact a doctor if your symptoms worsen or do not improve.
• If any of the side effects gets serious, or if you notice any side effect (see section 4) not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1. What Lactugal is and what it is used for

Lactugal contains the active ingredient lactulose. It is a type of sugar that is broken down into mild acids in the colon (the end part of the intestinal tract). These acids draw water into the colon and thereby soften the stool and easier to pass. It is not absorbed into your body.
Lactugal is used to treat constipation (infrequent bowl movement, hard and dry stools).
Lactugal is sometimes used in patients with a liver condition called hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). It helps prevent dangerous toxins from being absorbed into the blood stream.
2. What you need to know before you take Lactugal

Do not take Lactugal if:

• You are allergic (hypersensitive) to lactulose or any of the other ingredients of Lactugal (listed in section 6)
• You have a rare problem called ‘galactosaemia’.
• You suffer from any blockages of the bowel, other than constipation (for which you are taking Lactugal), digestive perforation or risk of digestive perforation

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

Warning and precautions:

Talk to your doctor or pharmacist before taking Lactugal if you suffer from any medical conditions or illnesses, in particular:

• If you are lactose intolerant (allergic to milk sugar)
• If you suffer from unexplained tummy ache
• If you have diabetes

If you have diabetes and are treated for hepatic encephalopathy, your dose of Lactugal 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 dosage (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolytes balance.

Please seek your doctor's advice if this medicine does not improve your condition after using for several days.

Children

In special circumstances your doctor may prescribe Lactugal for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. Lactugal should only be given to infants and smaller children if indicated as it can influence the normal reflexes for passing stools.
Other medicines and Lactugal

Lactugal has not been shown to interact negatively with other medicines. Always advise your doctor or pharmacist before taking any other medicines, including medicines obtained without a prescription.

Taking lactugal with food and drink

Lactugal 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. There is no potential risk during pregnancy and breast-feeding if lactugal is used in the recommended dosage.

No effects on fertility are to be expected.

Driving and using machines

Lactugal has no or negligible influence on your ability to drive or operate machinery.

Important Information about some of the ingredients of Lactugal

Lactugal may contain small amounts of milk sugar (lactose), galactose, epilactose or fructose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Lactugal

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

Taking this medicine

- Lactugal should be taken orally.
- You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 2 litres equal to 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 Lactugal is taken for long periods.
- It may take up to 2 to 3 days before Lactugal begins to have an effect.
- Once the medicine has started to work you may gradually reduce the amount you take.
Constipation:

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

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

Children aged 1 to 6 years:
The usual dose is 5 – 10 ml daily.

Infants under 1 year:
The usual dose is up to 5 ml 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 Lactugal to children (under 14 years) before consulting your doctor for prescription and careful supervision.

Hepatic encephalopathy (adults only)

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

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 Kidney or liver insufficiency: No special dosage recommendations exist.

If you take more Lactugal than you should

If you take more Lactugal than you should stop taking Lactugal and contact your doctor or local hospital immediately.

If you forget to take Lactugal

If you forget a dose of Lactugal, do not worry. Just take the forgotten dose as soon as you remember. However, if it is near the time for your next dose, ignore the missed dose and continue as usual with the next dose. Do not take a double dose to make up for a forgotten dose. If you forgot to take this medicine it might be because your symptoms have been relieved and you may not need to take it any more.

If you stop taking Lactugal

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, Lactugal can cause side effects, although not everybody gets them.
The following side effects have been reported with Lactugal:

**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

Flatulence may occur during the first few days of treatment. As a rule it disappears after a few days. When dos ages hi gher t han i nstructed a re us ed, a bdominal pa in and di arrhoea m ay occur. In such a case the dosage should be decreased.

If you use hi gh doses ( normally onl y a ssociated w ith hepatic e ncephalopathy, HE) f or a n 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 Yellow Card Scheme at: [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 Lactugal**
Keep Lactugal out of the sight and reach of children.
Do not store above 20° C. Do not refrigerate or freeze. Do not use Lactugal after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 Lactugal contains:
The active substance is Lactulose Solution. Each 5 ml contains (approx) 3.4 g lactulose. The other ingredients are banana flavour and quinoline yellow (E104).

What Lactugal looks like and contents of the pack:
Lactugal is available in 250 ml, 300 ml, 500 ml, 1,000 ml and 2,000 ml white plastic containers with plastic caps. Not all bottle sizes may be marketed.

Marketing authorisation holder and manufacturer
Intrapharm Laboratories Ltd, The Courtyard Barns, Choke Lane, Maidenhead, Berks SL6 6PT, UK.

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