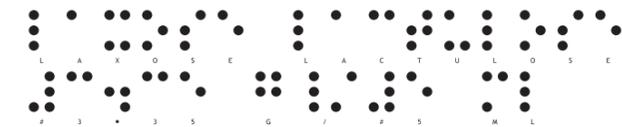


LAXOSE LACTULOSE #3.35 G/#5 ML



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PACKAGE LEAFLET: INFORMATION FOR THE USER
Laxose (Lactulose Solution BP) 3.35 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. Always take this medicine exactly as described in the leaflet or as your doctor or pharmacist has 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after several days.

What is in this leaflet:

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

1. WHAT LAXOSE IS AND WHAT IT IS USED FOR
Laxose contains lactulose which belongs to a group of medicines called osmotic laxatives. It works by encouraging normal bowel movements. Laxose is used for the treatment of constipation and is also used to treat brain disturbances associated with liver disease known as hepatic encephalopathy (accumulation in the bloodstream of toxic substances that are normally removed by the liver).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LAXOSE
Do NOT take Laxose if you:

- are allergic (hypersensitive) to lactulose or any of the other ingredients in the product (see Section 6 and end of Section 2)
- have a gastrointestinal obstruction (a blockage in the gut)
- gastrointestinal tract perforation or risk of gastrointestinal tract perforation
- require a galactose-free diet

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Laxose if you suffer from any medical conditions or illnesses, in particular:

- if you are diabetic
- if you are unable to digest milk sugar (lactose intolerant)
- if you suffer from unexplained tummy ache

You should not take Laxose if you suffer from:

- galactose or fructose intolerance
- Lapp lactase deficiency
- glucose-galactose malabsorption

If you have diabetes and are treated for hepatic encephalopathy, your dose of Laxose 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 electrolyte 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 Laxose for several days (2 to 3 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 Laxose for a child, infant or baby. In these cases your doctor will supervise the treatment carefully. Laxose should only be given to infants and smaller children if indicated as it can influence the normal

reflexes for passing stools.

Other medicines and Laxose
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but in particular the following:

- the anti-inflammatory drug mesalazine, used to treat inflammation of the digestive tract e.g. for ulcerative colitis or Crohn's disease.

Laxose with food and drink
Laxose can be taken with or without food. There are no restrictions on what you can eat or drink.

Pregnancy, breast-feeding and fertility
Laxose may be used during pregnancy and breast-feeding. No effects on fertility are to be expected. Ask your doctor or pharmacist for advice before taking any medication.

Driving and using machines
Laxose is unlikely to affect your ability to drive or to operate machinery.

Laxose contains lactulose which may contain small amounts of epilactose, galactose and fructose (all are types of sugar). If you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE LAXOSE
Always take Laxose exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Take your doses at the same time each day. Swallow the medicine quickly. Do not keep it in your mouth. You can take Laxose oral solution undiluted or diluted in some liquid.

Dosing in Constipation
The dose may be given once daily, for example during breakfast, or divided into two doses a day.

After a few days the starting dosage may be adjusted to the maintenance dose based upon your treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

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Patient	Starting dose daily	Maintenance dose
Adults & adolescents	15 - 45 ml	15 - 30 ml
Children, 7-14 years	15 ml	10 - 15 ml
Children, 1-6 years	5 - 10 ml	5 - 10 ml
Infants under 1 year	Up to 5 ml	Up to 5 ml

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 Laxose to children (14 years or under) before consulting your doctor for prescription and careful supervision.

Laxose encourages normal bowel action, and it may be two to three days before the full benefit is seen.

Dosing in Hepatic encephalopathy (for adults only)
The initial dose is 30 to 45 ml three to four times a day, which should then be adjusted to a daily dosage which produces 2-3 soft stools per day. Your doctor will advise you.

If you take more Laxose than you should
In case of overdose, you may experience diarrhoea and

abdominal pain. Contact your doctor or pharmacist if you have taken more Laxose than you should.

If you forget to take Laxose
If you forget to take a dose of Laxose, 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.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Laxose can cause side effects, although not everybody gets them.
STOP taking Laxose and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

The following side effects have been reported with this medicine:

Very Common (may affect more than 1 in 10 people)

- Diarrhoea

Common (may affect up to 1 in 10 people)

- Flatulence (wind)
- Vomiting
- Nausea (feeling 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LAXOSE
Keep out of the sight and reach of children. Do not use Laxose after the expiry date which is stated on the bottle or carton after EXP. The expiry date refers to the last day of that month. Do not store above

25°C. Do not 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.

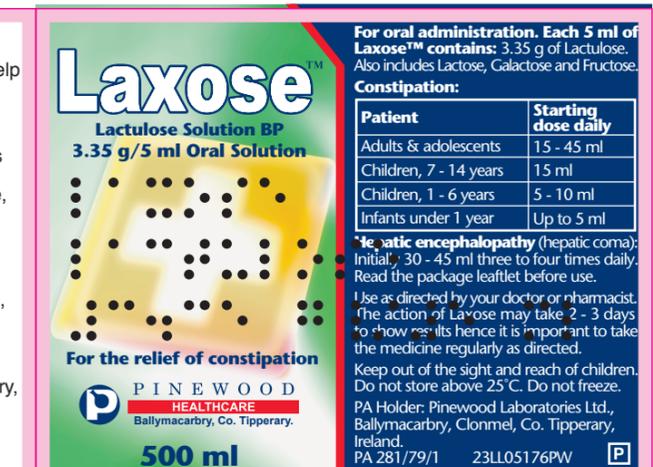
6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Laxose contains

- The active ingredient is lactulose. Each 5 ml of Laxose contains 3.35 g of lactulose.
- The other ingredients are lactose, galactose, fructose, epilactose, tagatose and purified water (see end of Section 2 for further information about the ingredients)

What Laxose looks like and contents of the pack
Laxose is a clear to almost clear, pale yellow solution, which is available in plastic bottles with plastic caps of pack sizes: 100 ml, 150 ml, 300 ml, 500 ml, 1 litre, 2.5 litres or 5 litres. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland
PA Number: 281/79/1

This leaflet was last updated in May 2017.



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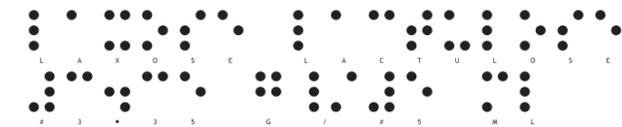
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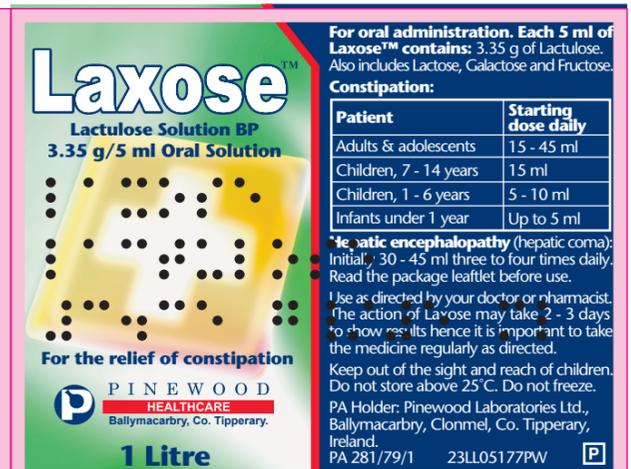
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