LACTULOSE

EASYLAC

3.35 g/5 mL Oral Solution
OSMOTICALLY ACTING LAXATIVE

PRODUCT DESCRIPTION:
Colourless to amber, syrupy liquid

FORMULATION:
Each 5 mL contains:
Lactulose ..... 3.35 g

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics
Lactulose is a synthetic disaccharide formed from D-galactose and fructose. Lactulose as a prebiotic substance strengthens the growth of bifidobacteria and lactobacilli, whereas Clostridium and Escherichia coli may be suppressed.

In the colon lactulose is metabolised by bacterial enzymes to short chain fatty acids mainly lactic and acetic acid as well as methane and hydrogen. This effect leads to a decrease of the pH-value and an increase of the osmotic pressure in the colon. This causes stimulation of peristalsis and an increase of the water content of the faeces.
Pharmacokinetics
Lactulose is practically not absorbed, because in man there is no corresponding disaccharidase available in the upper intestinal tract. Not being absorbed as such, it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged.

INDICATIONS:
• Symptomatic treatment of constipation
Indicated in adults and in children and adolescents aged 7 to 18 years. For children below 7 years, other dosage forms are available.

DOSAGE AND MODE OF ADMINISTRATION:
Posology
Lactulose may be administered diluted or undiluted. The dose should be titrated according to the clinical response. Lactulose may be given as a single daily dose or in two to three divided doses.
A single dose of lactulose should be swallowed in one and should not be kept in the mouth for an extended period of time.
The posology should be adjusted according to the individual needs of the patient. The starting dose can be adjusted after adequate treatment effect individually (maintenance dose). Several days (2-3 days) of treatment may be needed in some patients before adequate treatment effect occurs. In case of single daily dose, this should be taken at the same time of the day, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5-2 l/day, equal to 6-8 glasses).
If diarrhoea occurs, the dosing regimen should be reduced.
The duration of treatment has to be adopted according to the symptoms.

	Starting dose		Maintenance dose	
Adults	15-45 ml daily	1-3 sachets, corresponding to 10-30 g lactulose	15-30 ml daily	1-2 sachets, corresponding to 10-20 g lactulose

Older people
In elderly patients no special dosage recommendations exist.
Patients with renal or hepatic impairment
In patients with renal or hepatic insufficiency no special dosage recommendations exist.
Paediatric population

	Starting dose		Maintenance dose	
Adolescents over 14 years	15-45 ml daily	1-3 sachets, corresponding to 10-30 g lactulose	15-30 ml daily	1-2 sachets, corresponding to 10-20 g lactulose
Children (7-14 years)	15 ml daily	1 sachet, corresponding to 10 g lactulose	15 ml daily	1 sachet, corresponding to 10 g lactulose

For a precise dosing for infants, toddlers and children up to 6 years, lactulose is available in bottles.
Method of administration
Oral use.

CONTRAINDICATIONS:
- Hypersensitivity to the active substance or to any of the excipients.
- Use in patients with galactosaemia.
- Acute inflammatory bowel disease (ulcerative colitis, Crohn's disease), gastrointestinal obstruction or subocclusive syndromes, digestive perforation or risk of digestive perforation, painful abdominal syndromes of undetermined cause.

WARNINGS AND PRECAUTIONS:
In case of insufficient therapeutic effect after several days consultation of a physician is advised.
From the route of synthesis Lactulose may contain small amounts of sugars
(Not more than 67 mg/ml lactose, 100 mg/ml galactose, 67 mg/ml epilactose, 27 mg/ml tagatose and 7 mg/ml fructose).
Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose mal-absorption should not take this medicine.
Lactulose should be administered with care to patients who are intolerant to lactose.
Lactulose may contain more than 5 g lactose/galactose/epilactose depending upon the dose taken. This should be taken into account in patients with diabetes mellitus.15 ml of Lactulose contain 42.7 KJ (10.2 kcals) = 0.21 BU.
For patients with gastro-cardiac syndrome (Roemheld syndrome) lactulose should only be taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after lactulose intake, the dose should be reduced or the treatment should be discontinued.
Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.
For elderly patients or patients that are in bad general condition and take lactulose for a more than 6 months period, periodic control of electrolytes is indicated.
During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5-2 l/day, equal to 6-8 glasses).
Paediatric population
Use of laxatives in children should be exceptional and under medical supervision.
Lactulose should be administrated with caution in infants and small children with autosomal recessive hereditary fructose intolerance.
The defecation reflex may be altered during the treatment with lactulose.

PREGNANCY AND LACTATION:
Pregnancy
Limited data on pregnant patients indicate neither malformative nor foeto/neonatal toxicity. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
The use of Lactulose may be considered during pregnancy if necessary.

Lactation
Lactulose can be used during breastfeeding.

Effects on ability to drive and use machines
Lactulose has no or negligible influence on the ability to drive and use machines.

INTERACTIONS:
Lactulose may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.
With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.

ADVERSE DRUG REACTIONS:

Very common	≥ 1/10
Common	≥1/100 to < 1/10
Uncommon	≥1/1,000 to <1/100
Rare	≥1/10,000 to < 1/1,000
Very rare	< 1/10,000
Not known	cannot be estimated from the available data

Flatulence may occur during the first few days of treatment. As a rule it disappears after a couple of days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.
Gastrointestinal disorders

Very common (≥ 1/10):	Flatulence, abdominal pain,
Common (≥ 1/100 < 1/10):	Nausea and vomiting; if dosed too high, diarrhoea (sometimes including electrolyte imbalance).

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

OVERDOSE AND TREATMENT:
Symptoms:
If the dose is too high, the following may occur: diarrhoea and abdominal pain.
Management: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

STORAGE CONDITIONS:
Store at temperatures not exceeding 30°C. Protect from light. Keep medicine out of reach of children.

DOSAGE FORMS & PACKAGING AVAILABLE:
Dosage form: 3.35 g/5 mL Oral Solution
Packaging available: Amber PET bottle with ROPP cap x 100 mL + measuring cup (Box of 1's)

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act dispensing without prescription.

FDA Reg. No.: DRP-12458

Manufactured by:
PANACEA BIOTEC PHARMA LIMITED
Malpur, Baddi, Tehsil Nalagarh, District
Solan, Himachal Pradesh 173 205 India

Imported and Distributed by:
MEDINOVA PHARMACEUTICAL INC.
3270-C Armstrong Rd., Merville, Brgy. 201, Pasay City,
Metro Manila, Philippines

Date of first authorization: Aug 2022
Date of revision: Oct 2022