RODILOZA

Instructions for the medicinal product

Trade name: Rodiloza.
International Nonproprietary Name: Lactulose.
Dosage form: Solution for oral use.
Composition: Each 5 ml contains:
Lactulose 3.325 g.
(as Lactulose concentrate USP)
Pharmacotherapeutic group: Osmotically acting laxatives.
ATC Code: A06AD11.
Pharmacologic property:
Pharmacodynamics:
Lactulose, is metabolised in the colon by the sacchrolytic bacteria, producing low molecular weight organic acids, mainly lactic acid, which lower the pH of the colon contents, promote the retention of water by an osmotic effect, thus increasing peristaltic activity.
In portal systemic encephalopathy (PSE) or (pre)coma hepaticum, the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect, and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.
Pharmacokinetics:
Lactulose passes almost completely unabsorbed from the gastro-intestinal tract and essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria mainly into lactic acid and small amounts of acetic and formic acids. Urinary excretion of unchanged lactulose has been reported to be 3% or less.
Indications for use:
- constipation, chronic constipation, constipation in pregnancy, hemorrhoids;
- hepatic encephalopathy (serious liver disease, following by neuropsychiatric disorders);
- salmonellosis (acute disease of the digestive tract) except for generalized forms (infectious agents in blood);
- digestive disorders, food poisoning associated with putrefaction children up to 10 years;

Rodiloza can be used in pregnant and breastfeeding women, children older than 6 weeks, the elderly and people who had resection of hemorrhoidal bolus.
Contraindications:
- hypersensitivity to lactulose;
- patients with cramps, colic, nausea, vomiting, or any undiagnosed abdominal conditions;
- patients on galactose-free diets;
- undiagnosed rectal bleeding;
- congestive heart failure or hypertension.

With coution diabetes mellitus.
Dosage and directions for use:
Dosages can vary depending on the severity of the condition. Initially, a large dose is taken followed by a reduced maintenance dose after the first three days of treatment. Only one daily dose is necessary, preferably in the morning.
Initial dosage (3 days):
*Adults:*15 –45 ml (1-3 tablespoons).
Children 7-14 years: 15 ml (1 tablespoon).
Children 1 - 6 years: 5-10 ml (1-2 teaspoons).
Infants less than 1 year excluding the neonates: 5 ml (1 teaspoon).
Maintenance dosage:
Adults: 15-30 ml (1-2 tablespoons).
Children 7-14 years: 10 ml (2 teaspoons)
Children 1 - 6 years: 5-10 ml (1-2 teaspoons).
Infants less than 1 year excluding the neonates: 2,5 - 5 ml (1 teaspoon).
Management of hepatic encephalopathy.
Initial dosage: 30 - 50 mL 3 times daily; this dose is subsequently adjusted to produce 2 to 3 soft stools each day.
Shelf-life after first opening the immediate packaging: 28 days.

Side-effects:
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.
If high doses (normally only associated with portosystemic encephalopathy, PSE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea. Dosage should then be adjusted to obtain two or three formed stools per day.
Gastrointestinal disorders: flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhoea.
Overdose:
Symptom: diarrhoea and abdominal pain.
Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.
No specific antidote. Symptomatic treatment should be given.
Drug interaction:
Chronic use or overuse of lactulose may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract and may interfere with potassium-retaining effects of potassium-sparing diuretics.
Cautions:
There are no warnings or precautions for patients with any impaired organ function.
Rodiloza should be used with caution in patients exhibiting lactose intolerance.
The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of (pre)coma hepaticum is usually much higher and may need to be taken into consideration for diabetics.Due to the product's physiological mode of action it may take up to 48 hours before effects are obtained, however, the product does exhibit a 'carry over' effect which may enable the patient to reduce the dose gradually over a period of time.
Consultation with a physician is advised in cases where insufficient therapeutic effect occurs after several days of use.
Presentation:
150 ml glass bottle in carton box, withl measuring cup and instructions for use.
Storage:
Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after the expiry date.
Distribution Condition:
Non-prescribed medicine.