RUDOLAC

Osmotic laxative.

PRESENTATION

Oral solution, 250mL.

COMPOSITION

Active ingredient: Lactulose 3.5g/5mL.
Excipients: apricot flavor, mandarin flavor.

PROPERTIES

Lactulose (4-beta-D-galactoside-D-fructose) is a synthetic disaccharide consisting of galactose and fructose; it belongs to the group of laxatives that work by osmotic effect.
Lactulose reaches the colon where it breaks down into lactic and acetic acids under the influence of the lactobacilli and bacteroides; the small-intestinal disaccharidases cannot break down lactulose. The liberated acids cause water retention by osmosis as well as fecal softening. Evacuation of softer stools is induced by a reflex resulting from the dilation of the intestinal wall.
High dosage will lower the intestinal pH value and the content of ammonia is protonated. The absorption of the ammonium ions formed becomes difficult, while on the other hand, the diffusion of blood ammonia to the colon is favored. Lowering the pH value also leads to reducing the number of bacteria-producing ammonia.

INDICATIONS

1. Symptomatic treatment of constipation:
- For adults and elderly or bedridden patients as well as, under certain reserves, children;
- Following surgery.
2. Hepatic encephalopathy: used for prevention as well as for treatment, including precomatic and comatic states. Decrease in blood ammonia levels is often accompanied by an improvement of the psychological state and in electroencephalogram activity.

DOSAGE / DIRECTIONS FOR USE

1. Constipation: The daily dosage should be adjusted according to the observed results. Hence, it will normally take 24 to 48 hours from the beginning of the treatment to have defecation. The dose can be administered once daily in the morning, diluted or not, with a hot or cold beverage (milk, juice, coffee, yogurt or compote).
Adults: 10 to 20 g/day (15 to 30 mL). If necessary, the dose may be increased to 40g (60 mL). Based on the clinical pattern, this dose may be gradually reduced to a maintenance dose of 7 to 10 g/day (10 to 15 mL).
Elderly: 3.3 to 6.6g (4 to 10 mL) 2–3 times/day
Children: 0.2 to 0.4g (0.3 to 0.6 mL) per kg of body weight 3 - 4 times/day.
2. Hepatic encephalopathy: 20 to 30g (30 to 45 mL) 3 - 4 times/day. The dose should be adjusted individually.

CONTRAINDICATIONS

- Hypersensitivity to any of the ingredients, galactose or lactose intolerance, galactosemia, appendicitis, subileus and ileus;
- Stop use, as in all laxatives, in case of undiagnosed abdominal pain, nausea and gastrointestinal bleeding.

WARNINGS AND PRECAUTIONS

- Serum electrolytes (namely potassium, sodium and chloride) should be regularly determined particularly in patients with hepatic encephalopathy and in elderly people.
- In case of diarrhea, the dose should be reduced. If diarrhea persists, the medication should be stopped.
- Since the laxative contains lactose and galactose, certain precautions should be taken when using Rudolac in diabetic patients. 10 mL of Rudolac contains a maximum of 1.48g of assimilable carbohydrates, corresponding to 6.2 kcal or 26.4 kJ, and corresponding to 0.15 equiv. carbohydrates.
- Rudolac should not be taken simultaneously with other laxatives.

ADVERSE EFFECTS

Gastrointestinal disorders such as abdominal pain, meteorism with flatulence may occur occasionally. High doses may provoke nausea, vomiting and diarrhea.

PREGNANCY AND LACTATION

Rudolac can be taken during pregnancy and breast-feeding.

EFFECT ON DRIVING AND MACHINES USE

Rudolac has no effect on driving or the ability to operate machinery.

OVERDOSE

An overdose may cause diarrhea. In such case, the dosage should be reduced. If necessary, rehydration measures should be taken.

STORAGE

Do not use later than the date indicated under "EXP" on the bottle. Keep out of the reach of children.
Store at room temperature (15–25 °C).
Keep closed after opening.
Protect from sun.

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