Laxalac 3.35 g/5 ml

Pharmaceutical form: Solution for oral administration.

Composition: Each 5 ml contains: Active substance: lactulose 3.35g Excipient: menthol However, it may contain sugars from the manufacture process such as lactose, galactose and fructose.

Pharmacotherapeutic group: Osmotically acting laxatives.

Pharmacodynamics:

In the colon lactulose is broken down by colonic bacteria into low molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of colonic contents. These effects stimulate peristalsis of the colon and return the consistency of the stool. The constipation is cleared and the physiological rhythm of the colon is reinstated. In hepatic encephalopathy (HE) 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 is poorly absorbed after oral administration and 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:

1. For the treatment of constipation.
2. For the treatment of hepatic encephalopathy; hepatic coma

Contraidications:

- Hypersensitivity to the active substance or any of the excipients;
- Galactosaemia;
- Gastro-intestinal obstruction, digestive perforation or risk of digestive perforation

Posology and method of adimnistration:

The lactulose solution may be administered diluted or undiluted. Each dose may if necessary be taken with water or fruit juices, etc. Each 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. In case of single daily dose, this should be taken at the same time, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5–2 litres, equal to 6-8 glasses) during the day. For lactulose in bottles the measuring cup may be used. Dosing in constipation: Lactulose may be given as a single daily dose or in two divided doses using a measuring cap. After a few days the starting dosage may be adjusted to

the maintenance dose based upon treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

	Starting dose daily	Maintenance dose daily
Adults and 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	մինչև 5 ml	մինչև 5 ml

For a precise dosing for infants and children up to 7 years lactulose in bottles should be used. Dosing in hepatic encephalopathy (for adults only): Starting dose: 3 to 4 times daily 30-45 ml (6-9 x 5 ml tea spoonfuls). This dose may be adjusted to the maintenance dose to achieve two or three soft stools each day.

Paediatric population

The safety and efficacy in children (newborn to 18 years of age) with hepatic encephalopathy have not been established. No data are available.

Elderly patients and patients with renal or hepatic insufficiency

No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Precautions and warnings:

Painful abdominal symptoms of undetermined cause should be evaluated to exclude undiagnosed perforation or obstruction or undiagnosed disease/condition that predisposes to either before the treatment is started. In case of insufficient therapeutic effect after several days the dose and/or additional measures should be re-considered. Lactulose should be administered with care to patients who are intolerant to lactose (see section List of excipients). The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of hepatic encephalopathy is usually much higher and may need to be taken into consideration for diabetics. Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance. It should be taken into account that the defaecation reflex could be disturbed during the treatment. This product contains lactose, galactose and small amounts of fructose. Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pregnancy and lactation:

No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.

Laxalac can be used during pregnancy.

Lactation

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to lactulose is negligible. Laxalac can be used during breast-feeding.

Fertility

No effects are to be expected, since systemic exposure to lactulose is negligible.

Undesirable 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 hepatic encephalopathy, HE) 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

Tabulated list of adverse reactions

The following undesirable effects have been experienced with the below indicated frequencies in lactulose-treated patients in placebo-controlled clinical trials:

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)

MedDRA SOC	**Frequency category**			
	Very common	Common	Uncommon	Rare
Gastrointestinal disorders	Diarrhoea	Flatulence, abdominal pain, nausea, vomiting		
Investigations			Electrolyte imbalance due to diarrhoea	

Paediatric population

The safety profile in children is expected to be similar as in adults.

Package:

100ml glass bottle; 200ml; 250ml and 500ml polyethylene bottles. 1 bottle with measuring cup and leaflet insert in a carton box

Shelf-life:

Shef life is 3 years if kept in original undamaged package.

Storage:

Store below 25°C. Protect from direct sunlight.

Legal status:

Without prescription.