Summary Product Characteristics (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Laxalac®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lactulose 3.35 g/5 ml.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Oral solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Constipation:

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, for lactulose in bottles the measuring cup may be used.

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	Maintenance dose
Adults	15-45ml	10-30ml
Children 7-14	15ml	10-15ml
Children 1-6	5-10ml	5-10ml
Babies	Up to 5ml	Up to 5ml

If the maintenance dose is below 15 ml, lactulose in bottles should be used.

For a precise dosing for infants and children up to 7 years lactulose in bottles should be used.

Dosing in HE (for adults only):

Starting dose: 3 to 4 times daily 30-45 ml (6-9 x 5 ml 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 HE 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.

4.3 Contraindications

Contraindications:

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

4.4 Special warnings and precautions for use

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 6.1).

The dose normally used in constipation should not pose a problem for diabetics.

The dose used in the treatment of HE 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

4.6 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 breast-feeding 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.

4.7 Effects on ability to drive and use machines

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

4.8 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. See also overdose section 4.9.

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).

Gastrointestinal disorders

Flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhoea.

Investigations

Electrolyte imbalance due to diarrhoea.

Paediatric population

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

If the dose is too high, the following may occur:

Symptom: diarrhoea, loss of electrolytes 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC code: A 06A D11

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

The results of acute, sub-chronic and chronic toxicity studies in various species indicate that the compound has very low toxicity. The effects observed, appear to be more related to the effect of bulk in the gastrointestinal tract than to a more specific toxic activity. In reproduction and teratology experiments in rabbits, rats or mice no adverse effects were found.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Laxalac contains menthol and does not contain any other ingredient. However, it may contain sugars from the manufacture process such as lactose, galactose and fructose.

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Protect from direct sunlight.

6.5 Nature and contents of container

Glass bottles containing 100ml, and polyethylene bottles containing 200 ml, 250ml and 500 ml.

1 bottle with measuring cup and leaflet insert in a carton box.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Medical Horizon LLC

RA, Ararat province, Masis city, Masis station, Gortsaranain 22

8. MARKETING AUTHORISATION NUMBER(S)

8122/1, 13472/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02.10.2008

10. DATE OF REVISION OF THE TEXT

July 2019