Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

B-Lact Syrup

2. Qualitative and quantitative composition

Each 5ml contains: Lactulose ……3.35gm
For the full list of excipients, see section 6.1

3. Pharmaceutical form

Clear, pale yellow to yellowish brown solution

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of constipation.
For the treatment of hepatic encephalopathy (HE): treatment and prevention of hepatic coma or precoma

4.2 Posology and method of administration

Posology
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.
For lactulose in 15 ml single dose sachets the corner of the sachet should be torn off and contents taken immediately.

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.

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 hepatic encephalopathy (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 impairment
No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Method of administration
For administration by the oral route

4.3 Contraindications

• Hypersensitivity to the active substance substance or to any of the excipients listed in section 6.1.
• Galactosaemia.
• Gastro-intestinal obstruction, digestive perforation or risk of digestive perforation.

4.4 Special warnings and precautions for use

Since B-Lact contains galactose (less than 2.2g/15ml) and lactose (less than 1.2g/15ml), it should be used with caution in diabetics. Care should be taken in patients who are lactose intolerant. Patients who develop gastrointestinal symptoms (flatus, bloating and diarrhea) with the use of dietary fiber should exercise caution in the use of lactulose.

4.5 Interaction with other medicinal products and other forms of interaction

None reported

4.6 Pregnancy and Lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.
Lactulose can be used during pregnancy when considered necessary by the physician.
Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to lactulose is negligible.
This medicine 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.

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 diarrhea may occur. In such a case the dosage should be decreased. See also overdose section 4.9.
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 diarrhea. Dosage should then be adjusted to obtain two or three formed stools per day.
Because the following reactions were reported spontaneously from a population of uncertain size it is not possible to reliably estimate their frequency.

Gastrointestinal disorders
Common effects include: flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhea. Investigations Electrolyte imbalance due to diarrhea.

Investigations
Electrolyte imbalance due to diarrhea.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

If the dose is too high, the following may occur:
Symptom: diarrhea and abdominal pain.
Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhea 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

Mechanism of action
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

None

6.2 Incompatibilities

None known

6.3 Shelf-Life

24 months
Use within 12 months of first opening

6.4 Special Precautions for storage

Store at temperature below 30oC. Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolong exposure to freezing temperature may cause change to a semisolid too viscous to pour. Viscosity will return to normal upon warming to room temperature.
Protect from light.

6.5 Nature and Content of container

Round amber glass bottle 120ml sealed with PP Cap further packed in carton with insert and plastic cup.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
BROOKES PHARMA (PRIVATE) LIMITED

8. Marketing Authorization Number
CTD8574

9. Date of first authorization/renewal of the authorization
18/04/2024

10. Date of revision of the text
18/05/2025