Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

B-Lact Syrup 3.335 g/5 ml

2. Qualitative and quantitative composition

Each 5ml contains Lactulose 3.335 g.

Excipients with known effect: Also contains small amounts of lactose, galactose, fructose, tagatose or epilactose.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup

Clear, pale yellow to yellowish brown solution

4. Clinical particulars

4.1 Therapeutic indications

1. For the treatment of constipation.

2. 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 syrup 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.

Lactulose in bottles:

Age Group	**Starting dose daily**	**Maintenance dose daily**
Adults and adolescents	15-45 ml, corresponding to 10-30 g lactulose	15-30 ml, corresponding to 10-20 g lactulose
Children (7-14 years)	15 ml, corresponding to 10 g lactulose	10-15 ml, corresponding to 7-10 g lactulose
Children (1-6 years)	5-10 ml, corresponding to 3-7 g lactulose	5-10 ml, corresponding to 3-7 g lactulose
Infants under 1 year	up to 5 ml, corresponding to up to 3 g lactulose	up to 5 ml, corresponding to up to 3 g lactulose

* 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 has 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. B-Lact contains galactose (less than 2.2g/15ml), it is contraindicated in patients who require a low galactose diet.

• Gastro-intestinal obstruction, digestive perforation or risk of digestive perforation.

4.4 Special warnings and precautions for use

Consultation of a physician is advised in case of:

- 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 reconsidered.

Long term use of this product is inadvisable except under medical supervision.

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. A dose of 30 ml provides 116 KJ (28 kcals) and is unlikely to adversely affect 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 diarrohea and disturbance of the electrolyte balance. As diarrhoea induced by lactulose may lead to electrolyte imbalance, use with caution in patients prone to developing electrolyte disorders (e.g. patients with renal or hepatic impairment, patients receiving concomitant diuretics).

Paediatric population

Use of laxatives in children should be exceptional and under medical supervision.

It should be taken into account that the defecation reflex could be disturbed during the treatment.

Important information regarding the ingredients of this medicine

This medicine contains small amounts of lactose, galactose, fructose, tagatose and epilactose. Patients with rare hereditary problems of galactose or fructose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Although lactulose could theoretically delay the intestinal release of mesalazine from modified-release preparations, a study found no evidence that lactulose influenced the release or disposition of mesalazine in healthy volunteers.

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 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)].

MedDRA SOC	**Frequency category**			
	Very common	**Common**	**Uncommon**	**Not Known**

Immune system disorders				hypersensitivity reactions
Gastrointestinal disorders	Diarrhoea	Flatulence, abdominal pain, nausea, vomiting		
Skin and subcutaneous tissue disorders				Rash, pruritus, urticaria
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 authorizationof the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal products. 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:

Symptoms:

diarrhoea, loss of electrolyte 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: **A06AD11**

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

Lactulose does not contain any excipients, but may contain small amounts of related sugars (e.g. lactose, galactose, epilactose, fructose) from the route of synthesis.

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

36 months

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

BROOKES PHARMA PRIVATE LIMITED
PLOT NO. 58 & 59, SECTOR 15, KORANGI INDUSTRIAL

8. Marketing Authorization Number

CTD8574

9. Date of first authorization/renewal of the authorization

18/04/2024

10. Date of revision of the text

06/05/2025