Lactulose

B-Lact

3.35 g/5 mL Syrup
Laxative

Formulation:
Each 5 mL contains:
Lactulose USP.....3.35 g

PRODUCT DESCRIPTION:
Clear pale yellow solution

INDICATIONS:
Treatment of constipation and hepatic encephalopathy.

DOSAGE AND ADMINISTRATION:
Lactulose is a synthetic dissacharide osmotic laxative used in the treatment of constipation and in hepatic encephalopathy. Lactulose is broken down by colonic bacteria mainly into lactic acid. This exerts a local osmotic effect in the colon resulting in increased faecal bulk and stimulation of peristalsis. It may take up to 48 hours before an effect is obtained. When larger doses are given for hepatic encephalopathy the pH in the colon is reduced significantly and the absorption of ammonium ions and other toxic nitrogenous compounds is decreased, leading to a fall in blood ammonia concentration and an improvement in mental function. Lactulose is usually given as a solution containing about 3.35 g of Lactulose per 5 mL with other sugars such as galactose and lactose; an oral powder formulation is also available in some countries. In the treatment of constipation, the usual initial dose is 10 to 20 g (15 to 30 mL) given daily by mouth in a single dose or in 2 divided doses; doses up to 45mL daily of the solution (or up to 40 g of the reconstituted oral powder formulation) have been given. The dose is gradually adjusted according to the patient's needs. Children aged 5 to 10 years may be given initial doses of 10 mL twice daily; 1 to 5 years, 5 mL twice daily; under 1 year, 2.5 mL twice daily.

In hepatic encephalopathy, 60 to 100 g (90 to 150 mL) is given daily by mouth in 3 divided doses. The dose is subsequently adjusted to produce 2 or 3 soft stools each day. Lactulose solution 300 mL mixed with 700 mL of water or sodium chloride 0.9% has been used as a retention enema; the enema is retained for 30 to 60 minutes, repeated every 4 to 6 hours until the patient is able to take oral medication

PHARMACOKINETICS:
Taken orally, Lactulose passes essentially unchanged into the large intestine where it is metabolized by saccharolytic bacteria with the formation of simple organic acids, mainly lactic acid an small amounts of acetic and formic acids. The small amount of absorbed Lactulose is subsequently excreted unchanged in the urine.

PRECAUTIONS:
Lactulose should not be given to patients with galactosaemia or intestinal obstruction. It should not be used in patients on a low galactose diet and care should be taken in patients with lactose intolerance or in diabetic patients because of the presence of some free galactose and lactose.

OVERDOSE & TREATMENT:
There have been no reports of accidental overdosage. In the event of overdosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be withdrawn.

CONTRAINDICATIONS:
Since Lactulose contains galactose (<1.65 g/15mL), it is contraindicated in patients who require a low galactose diet, Galactosemia and Bowel obstruction. Hypersensitivity to any components of Lactulose.

ADVERSE DRUG REACTIONS:
Lactulose may cause abdominal discomfort associated with flatulence or cramps. Nausea and vomiting have occasionally been reported after high doses. Some consider the taste to be unpleasant, this can be minimized by dilution in water, fruit juice, or milk, or by mixing the dose with food. Prolonged use or excessive dosage may result in diarrhea with excessive loss of water and electrolytes, particularly potassium. Hypernatraemia has been reported.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary.

Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.

Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperature not exceeding 30°C.

AVAILABILITY:
Amber glass bottle x 120 mL with Measuring cup (Box of 1's)

FDA Registration Number: DRP 5264

Date of Renewal of Authorization: 11 April 2014

Date of Revision of Package Insert: 29 December 2016

Manufactured by:
Fresenius Kabi Austria GmbH
Estermannstrasse 17,
A-4020 Linz, Austria.

For:
Brookes Pharma (Private) Limited
Plot No. 58, Sector 15, Korangi Industrial Area,
Karachi-Pakistan.

Brookes

Imported & Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354, Aguirre Ave., Phase-III, BF Homes,
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Certification

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