LACTULOSE SOLUTION USP 3.35 gm / 5 ml

POM

COMPOSITION
Each 5 ml contains:
Lactulose Concentrate USP
Equivalent to Lactulose 3.35 gm
Aqueous base Q.S.
Approved colour used

PHARMACOLOGICAL CLASSIFICATION
Synthetic Disaccharide, Osmotic Laxative

PHARMACOLOGICAL ACTIONS
Lactulose produces an osmotic effect in the colon resulting from biodegradation by colonic, bacterial flora into lactic, formic and acetic acid. Lactulose reduces intestinal absorption of ammonia.
Pharmacokinetics
Lactulose passes almost completely unabsorbed from the gastro-intestinal tract and essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria mainly into lactic acid and small amounts of acetic and formic acids. Urinary excretion of unchanged lactulose has been reported to be 3% or less.

INDICATIONS
Constipation, Hepatic encephalopathy, Chronic portal hypertension.

CONTRAINDICATIONS
Lactulose is contra-indicated in:
Patients with cramps, colic, nausea, vomiting, or any undiagnosed abdominal conditions.
Patients on galactose-free diets.
Undiagnosed rectal bleeding.
Congestive heart failure or hypertension.
Diabetes mellitus.
Hypersensitivity to the ingredient

WARNINGS AND PRECAUTIONS
Lactulose should not be given to children up to 6 years of age unless prescribed by a physician. Since children are not able to describe their symptoms precisely, proper diagnosis should precede the use of a laxative. This will avoid the complication of an existing condition (e.g. appendicitis) or the appearance of more severe side effects. Lactulose should not be given to patients with intestinal obstruction. and on a low-galactose diet. Care should also be taken in patients with lactose intolerance or in diabetics because of the presence of some free galactose and lactose. In the event that an unusual diarrheal condition occurs, contact your physician.
Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.
Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no known human data on long-term potential for carcinogenicity, mutagenicity, or impairment of fertility.
Pregnancy: Lactulose solution should be used with caution during the first trimester of pregnancy.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lactulose solution is administered to a nursing woman.
Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

DOSAGE AND ADMINISTRATION
Constipation:
Adults: Initially 15 ml twice daily.
Children: 1 to 5 years – 5 ml twice daily.
5 to 10 years – 10 ml twice daily

Dosage may vary depending on the condition. The above dosage serves as a guide. Eventually the dose should be adjusted, usually reduced to meet the needs of the individual.
Hepatic encephalopathy: Initially 30ml to 50ml, 3 times daily; adjust dose to produce 2 or 3 soft stools daily.
Method of administration: Oral.

ADVERSE EFFECTS
Less frequently occurring: Gastro-intestinal disorders, Bloating, Cramping, Nausea, Diarrhoea, Gas formation, increased thirst.

DRUG INTERACTIONS
Chronic use or overuse of lactulose may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract and may interfere with potassium-retaining effects of potassium-sparing diuretics.
Non-absorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH.

OVERDOSE
Prolonged use or excessive dosage may result in diarrhoea with excessive loss of water and electrolytes particularly potassium. It may also result in hypernatraemia and exacerbation of hepatic encephalopathy. Treatment should be symptomatic and supportive.

PRESENTATION:
Bottle Pack

STORAGE CONDITION:
Store below 30°C.Protect from light.

Manufactured by :
LPL LINCOLN PHARMACEUTICALS LTD.
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