LIVOLUK
LACTULOSE SOLUTION USP

DESCRIPTION

LIVOLUK solution is a brand of Lactulose, a synthetic disaccharide which is highly useful in the management of portal systemic encephalopathy and also constipation. LIVOLUK is colourless to amber, syrupy liquid.

COMPOSITION

Each 15 ml contains:

Lactulose 10 g (As Lactulose concentrate USP)

PHARMACOLOGY

Lactulose, a synthetic disaccharide analog of lactose containing galactose and fructose, decreases blood ammonia concentrations and reduces the degree of portal systemic encephalopathy. The human gastrointestinal tissue does not have any enzyme capable of hydrolysis of this disaccharide; as a result oral dose passes to the colon virtually unchanged. After reaching the colon, lactulose is metabolized by bacteria (Lactobacillus, Bacteroides, Escherichia coli and Streptococcus faecalis) resulting in the formation of low molecular weight acids (lactic acid, formic acid, acetic acid) and carbon dioxide. These products produce an increased osmotic pressure and slightly acidify the colonic contents, resulting in an increase in stool water content and stool softening. Since the colonic contents are more acidic than the blood, ammonia can migrate from the blood into the colon. The acid colonic contents convert Ammonia (NH₃) to the ammonium ion [NH₄]⁺, trapping it and preventing its absorption. The laxative action of the lactulose metabolites then expels the trapped ammonium ion [NH₄]⁺ from the colon. Lactulose may also interfere with glutamine dependent non-bacterial ammonia production in the intestinal wall.

PHARMACOKINETICS

Lactulose is poorly absorbed. When given orally, only small amounts reach the blood. Urinary excretion is less than or equal to 3% and is essentially complete within 24 hours. Lactulose exerts its effect only in the colon. Transit time through the colon may be slow, therefore, 24-48 hours may be required to produce a normal bowel movement.

Special Population

Elderly and debilitated: Such patients who receive lactulose for > 6 months should have serum electrolytes and carbon dioxide measured periodically.

Usage in pregnancy and lactation: Lactulose has been found to be safe and well-tolerated during four weeks of treatment in pregnant women. Also, Lactulose does not appear in breast milk, so it can be continued during lactation.

Children: The safety and efficacy of lactulose in the treatment of chronic constipation in children aged over 10 months has been reasonably established.
INDICATIONS
Treatment of constipation, chronic constipation, after haemorrhoidectomy, in elderly after Barium meal examination, in bed ridden or institutionalized patients and others. Prevention and treatment of portal systemic encephalopathy including the stages of hepatic precoma and coma. Livoluk reduces blood ammonia levels by 25% to 50%. This generally parallels improved mental state and EEG patterns.

CONTRAINDICATIONS
Patients who require a low galactose diet.

WARNINGS
Electro-cautery Procedures: A theoretical hazard of explosion due to accumulation of H2 gas may exist for patients being treated with lactulose who may undergo electrocautery procedures during proctoscopy or colonoscopy. Hence, patients should have a thorough bowel cleansing with a nonfermentable solution before pursuing the procedure.

PRECAUTIONS
Diabetics: Lactulose solution contains galactose (<2.2 g/15 ml) and lactose(<1.2 g/15 ml). Use with caution in these individuals.
Concomitant laxative use: Do not use other laxatives, especially during the initial phase of therapy for Portal Systemic Encephalopathy; the resulting loose stools may falsely suggest adequate lactulose dosage.
Monitoring: In Portal Systemic Encephalopathy, electrolyte disturbances may require intensive monitoring and another specific therapy.

DRUG INTERACTIONS
Neomycin and other anti-infective agents may eliminate certain colonic bacteria and may interfere with the desired degradation of lactulose and prevent the acidification of colonic contents. Monitor the patient if concomitant oral infectives are given
Antacids: Nonabsorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH.

ADVERSE REACTIONS
Gaseous distention with flatulence or belching and abdominal discomfort, such as cramping may occur. Excessive dosage can lead to diarrhoea, nausea and vomiting.

OVERDOSAGE AND TREATMENT
There have been no reports of accidental overdosage. It is expected that diarrhoea and abdominal cramps would be the major symptoms. Discontinue the medication.

DOSAGE AND ADMINISTRATION
Treatment of Constipation: 15 to 30 ml daily, increased to 60 ml/day, if necessary.
Prevention and treatment of portal-systemic encephalopathy: Adults: 30 to 45 ml, or 4 times daily. Adjust dosage everyday or two to produce 2 or 3 soft stools daily. Hourly doses of 30 to 45 ml may be used to induce rapid laxation in the initial phase of the therapy. When the laxative effect has been achieved, reduce dosage to recommended daily dose. Improvement may occur within 24 hours, but may not begin before 48 hours or later. Continuous long-term therapy is indicated to lessen severity and prevent recurrence of portal systemic encephalopathy.
Children: Recommended initial daily dose in infants is 2.5ml twice daily. Children aged between 1 - 5 years can be given 5 ml twice daily. For older children and adolescents, the initial dose of 10ml twice daily can be administered. The total daily dose is 40 to 90 ml. If the initial dose causes diarrhoea, reduce immediately. If diarrhoea persists, discontinue use.
STORAGE INSTRUCTIONS
Preserve in tight container, preferably at a temperature between 2°C and 30°C. Avoid subfreezing temperatures.

REFERENCES