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Laxitol™

(LACTITOL)

10 gm / 15 ml

لیکسیٹول

COMPOSITION:
Each 15 ml contains:
Lactitol Monohydrate USP ..... 10 gm.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:
LAXITOL contains Lactitol Monohydrate. Lactitol is a synthetic lactulose-like disaccharide. It is derived from lactose and is minimally absorbed following oral administration. It is more palatable, better tolerated and produces a more predictable cathartic activity than lactulose. Lactitol has caloric value of 2 kcal/g (8.5KJ/g) and has no effect on blood glucose levels. It can therefore be given to diabetic patients.

PHARMACOLOGY:
Mechanism of Action:
Lactitol is a disaccharide derivative consisting of galactose and sorbitol which is only minimally absorbed and is not hydrolyzed by the disaccharidases of the gastrointestinal tract and thus reaches the colon unchanged. In the colon it is broken down to short chain organic acids, mainly acetic, propionic and butyric acid, by the intestinal flora, in particular by the bacteroides and lactobacilli, thus acidifying the contents of the colon. The effect of this acidification is to reduce the absorption of ammonia. The transformation of Lactitol into low molecular weight organic acids results in an increase in osmotic pressure in the colon, thereby causing an increase in the stool water content and stool volume, which explains the laxative effect. Lactitol produces its effect in the lumen of the colon, where it is virtually 100% bioavailable. The mechanism of action of Lactitol in hepatic encephalopathy is most likely related to suppression of the absorption of unionized ammonia via lowering of colonic pH; a cathartic action also enhances fecal nitrogen excretion and decreases intestinal transit time, with a reduction in the time for production and absorption and other potential toxins.
Pharmacokinetics:
Lactitol is not significantly absorbed in the small intestine; only 0.5% to 2% of a dose is partially absorbed as unchanged Lactitol. 64% of the dose is absorbed by the colonic mucosa as volatile fatty acids, with 6.5% excreted in the feces. Small amounts of unchanged Lactitol appear in the urine (2% or less of a dose).

INDICATIONS:
LAXITOL is indicated for the following:
- Treatment of constipation
- Prevention and treatment of Hepatic Encephalopathy

DOSAGE AND ADMINISTRATION:
Constipation:
LAXITOL syrup should be administered once daily, in the morning or evening, at meal times.
The usual recommended dose is as follows:
Adults: 15 ml to 30 ml per day
Children: The mean dosage is 0.25 g/kg body weight daily
2-6 years old: 10 ml per day
Above 6 years: 10-15 ml per day
Hepatic encephalopathy:
The general recommended dose for LAXITOL is 0.5 to 0.7 g/kg body weight daily, divided into three daily doses with meals. The dosage should then be adjusted to produce two soft bowel movements daily.
- For the prevention of hepatic encephalopathy the recommended dose of LAXITOL is 30 ml once daily in the evening.
- For acute and/or decompensated stage of the disease the recommended dose is 45-90 ml divided in three doses with main meals.

CONTRAINDICATIONS:
- Appendicitis
- Patients with intestinal obstruction, or an underlying organic lesion of the gastrointestinal tract
- Patients with unexplained abdominal pain or bleeding
- Patients with ileostomy or colostomy
- Hypersensitivity to the drug or any other component of the formulation
- Galactosemia

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WARNINGS & PRECAUTIONS:
Absorption of lactate from colonic metabolism of Lactitol can potentially result in acid-base disturbances, and diarrhea induced by Lactitol can be associated with hypokalemia and hyponatraemia. In more severe cases, dehydration or hypokalemia may arise, which can lead to heart or neuromuscular dysfunctions, especially in the case of the simultaneous treatment with cardiac glycosides, diuretics or corticosteroids. Periodic monitoring of serum electrolytes, blood glucose and blood lactate is suggested. If watery stools are noticed, one should either reduce the quantity of administration or suspend administration. As with all laxatives, any preexisting electrolyte or water balance abnormalities must be corrected. Blood electrolyte levels should be monitored regularly in elderly or debilitated patients on long term treatment.
Patients who complain of nausea should be advised to take Lactitol with meal. In the presence of intestinal bloating start treatment with low doses indicated, gradually increasing them according to clinical response. The abuse of laxatives can cause dependency (and, therefore, the possible need to progressively increase the dosage), chronic constipation and loss of normal intestinal functions (intestinal atony).

PREGNANCY AND LACTATION:
This drug should be used in pregnancy only if clearly needed. Although there have been no studies on the elimination of Lactitol in breast milk, it is unlikely that the use of Lactitol while breast feeding would have any clinical effect on the child, because its absorption is minimal. But the potential benefits of the drug should outweigh the risks before prescribing this drug to nursing mothers.

DRUG INTERACTIONS:
If broad spectrum antibacterial agents and antacids are administered along with Lactitol, it can cause a reduction in acidification effect of Lactitol on intestinal microflora and consequently limiting therapeutic efficacy Laxatives can reduce the time spent in the intestine and consequently the absorption of other drugs administered by mouth. Hence, laxatives should not be taken at the same time as other medicines: after taking a medicine, wait at least 2 hours before taking the laxative. Lactitol can increase the potassium losses caused by other medicines (e.g. thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B). Potassium deficiency may increase risk of toxic effects of cardiac glycosides in patients receiving concomitant therapy. Lactitol can increase digitalis toxicity. Concomitantly administration of Lactitol with neomycin can cause an increase in neomycin activity.

ADVERSE EFFECTS:
Patients may experience flatulence and abdominal cramps at the beginning of treatment, especially with high doses of medication. These effects disappear or are reduced to normal after a few days of treatment. Other less frequent side effects include abdominal discomfort, nausea, dyspepsia, epigastric pain, urgency, or anal pruritus and vomiting in rare cases. Diarrhoea occurs generally with excessive doses of Lactitol; but some patients may experience diarrhea at the recommended dosage. A reduction in dosage will overcome this.

OVERDOSAGE:
Excessive doses may cause abdominal pain and diarrhea; consequent losses of liquids and electrolytes must be replaced.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight and moisture.
- Tightly close the cap after use.
- Avoid freezing.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
LAXITOL Syrup : Bottle of 120 ml.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
استعمال کے بعد ڈھکن کو اچھی طرح بند کر دیں۔
منجمند ہونے سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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