8027459-9093

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

TorRelax

(Lactitol Monohydrate Syrup 66.67 % w/v)

DELICIOUS ORANGE FLAVOURED

Composition

Each 15 ml contains :

Lactitol Monohydrate U.S.P.	10 g
Benzoic Acid I.P. (as preservative)	0.0225 g
Flavoured aqueous base	q.s.
Colours : Sunset Yellow FCF & Ponceau 4R	

Clinical Pharmacology

Lactitol is a sugar alchohol derived from Lactulose. It is obtained from lactose and is least absorbed following oral administration. It is more palatable, better tolerated and produces a more predictable cathartic activity than lactulose. Lactitol monohydrate has calorific value of 2kcal/g (8.5kj/g) and has no significant effect on blood glucose levels.

Mechanism of Action

Lactitol is sugar alchohol consisting of galactose and sorbitol, which is minimally absorbed and is not hydrolyzed by the disaccharidases of the gastrointestinal tract and thus reaches the colon unchanged. It breaks down in the colon to short chain organic acid mainly acetic, propionic and butyric acid, by the intestinal flora, in particular by the bacteroides and lactobacilli, thus acidifying the content of the colon. The effect of this acidification is to reduce the absorption of ammonia. The transformation of lactitol into low molecular weight organic acid results in an increase in osmotic pressure in the colon thereby causing an increase in the stool water content and stool volume which explain the laxative effect.

The mechanism of action in hepatic encephalopathy is related to suppression of the absorption of unionized ammonia via lowering of colonic pH, a cathartic action also enhances fecal nitrogen excretion and decrease intestinal transit time, with a reduction in the time for production and absorption of ammonia and other potential toxins. Other speculated mechanism includes stimulation of ammonia incorporation into bacterial protein and intestinal ammonia generation.

Pharmacokinetics

Lactitol is not significantly absorbed in the small intestine, only 0.5% to 2% of a dose is partially absorbed. Upon reaching the colon, lactitol is rapidly and extensively metabolized to volatile fatty acids by the bacterial metabolism resulted in carbon dioxide formation and loss of 27.4% of the dose, 64% of the dose was calculated to be 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 % of less of a dose)

Indications

Lactitol syrup is indicated for :

Treatment of constipation

Prevention and treatment of hepatic encephalopathy

Contra-indications

Appendicitis

Patients with intestinal obstruction, or in cases of unexplained abdominal pain or bleeding.

Hypersensitivity to the drug or other component of the formulation.

Galactosemia

Warning and Precautions

Absorption of lactate from colonic metabolism of lactitol can potentially result in acid-base disturbance. Diarrhea induced by lactitol can be associated with hypokalemia and hypernatremia. Potassium deficiency may increase the risk of toxic effects of glycosides in patients receiving concomitant therapy.

Periodic monitoring of serum electrolytes, blood glucose and blood lactate is suggested.

If watery stools are noticed, one either reduce the quantity of administration or suspend administration. As with all Laxatives, any pre-exciting electrolyte or water balance abnormalities must be corrected. Blood electrolyte levels should be monitored regularly in elderly or debilitated patients on long term treatment.

Patient who has complain of nausea should be advised to take lactitol with meal.

Lactitol is not recommended in case of ileostomy.

Fecal impaction should be treated by alternative methods prior to using lactitol.

Following treatment with lactitol, hydrogen may be accumulated in the bowel. Patients who need to undergo electrocauterisation procedures should therefore have a bowel cleaning with a non fermentable solution.

All cases of chronic constipation should first be treated by a fibre rich diet, intake of liquids or physical activity.

Prolonged use of laxatives without interruption should be avoided.

Typical symptoms of laxative overdose include abdominal pain, weakness, fatigue, thirst, vomiting, edema, bone pain (due to osteomalacia), fluid and electrolyte imbalance, hypoalbuminemia (due to protein losing gastroenteropathy) and syndromes that mimic colitis.

If presence of air is perceived in the intestine, it is advisable to begin the treatment with the minimum dose, gradually increasing based on the therapeutic response. 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.

Pregnancy & Lactation

Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women with child bearing potential and nursing mothers.

Therefore, lactitol can be prescribed only if the potential benefits justify the potential risk to the fetus.

Although there have been no studies on the excretion of lactitol in breast milk, it is unlikely that the use of lactitol while breast feeding could have any clinical effect on the child, because its absorption is minimal.

But the potential benefits of drug treatment should be weighed against potential risks before prescribing this drug during lactation.

Drug Interactions

Lactitol can increase the potassium losses caused by other medicines (e.g. thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B).

Potassium deficiency may increase the risk of toxic effects of glycosides in patients receiving concomitant therapy.

Lactitol can also increase digitalis toxicity. Concomitant administration of lactitol with neomycin can cause an increase in neomycin activity.

If large spectrum antibacterial agents are administered along with lactitol it can cause a reduction in acidification effect on intestinal microflora and consequently limiting therapeutic efficacy.

Side Effects

Abdominal distension or cramp and flatulence have occurred most frequently, these effects are most prevalent during the first 10 days of treatment and tend to subside on continued administration. Other less frequent side effects include abdominal discomfort, nausea, dyspepsia, epigastric pain, urgency of defecation, borborygmi or anal pruritus and vomiting in rare cases.

Diarrhea occurs generally with excessive doses of lactitol but some experience diarrhea at the recommended dosage. A reduction in dosage will overcome this problem. Severe flatulence, nausea and epigastric pain have occasionally necessitated withdrawal of lactitol therapy.

Absorption of lactate resulting from colonic metabolism of Lactitol can potentially result in acid-base disturbances. Diarrhea induced by lactitol can be associated with hypokalemia and hypernatremia.

Overdose

The appearance of diarrhea and abdominal cramps is a sign of overdosage which requires dose reduction. Overdose may also cause a shift in serum electrolytes which may require corrective therapy. In case of overdosage, periodic monitoring of serum electrolytes is suggested.

Dosage and administration

Constipation: Lactitol Syrup should be administered once daily in the morning or evening (at mealtime). The choice between morning and evening should be left to the patient depending on his or her individual response to the product. The laxative effect usually occurs a few hours after taking Lactitol Syrup. The patient should be told that in some case laxative action may not begin until the 2nd and 3rd day after the initial dose. Patient should be advised to maintain an adequate daily intake of fluid.

Adult patient :

The usual recommended dose of Lactitol Syrup is 15 to 30 ml per day.

Pediatric patient :

The usual recommended dose of Lactitol Syrup for children between age group 2 to 6 years is 10ml per day. For children above age of 6 years the recommended dose is 10 to 15 ml per day.

Hepatic encephalopathy

For the prevention of hepatic encephalopathy the recommended dose of Lactitol Syrup is 30ml once daily in the evening.

The usual recommended dose for the treatment of acute hepatic encephalopathy is 45 to 90 ml divided into 3 dose along with the main meals.

Incompatibilities

None reported

Storage

Store in a well closed container at a temperature not exceeding 30^{o}C. Do not freeze.

Keep all medicines out of reach of children.

Expiry Date

Do not use later than the date of expiry.

Presentation

Torrelax is available as 10g/15ml in 100 and 200 ml pet bottle.

torrent

Marketed by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

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