Torrelax

For the Use of a Registered Medical Practitioner or a Hospital or a Laboratory Only.

Abbreviated Prescribing information for Torrelax (Lactitol Monohydrate Syrup 66.67 % w/v) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Lactitol is a sugar alcohol derived from Lactulose with cathartic activity.

INDICATION: It is indicated in treatment of constipation and prevention and treatment of hepatic encephalopathy.

DOSAGE AND ADMINISTRATION: *For Constipation*: 15 to 30 ml per day *(for adults)* and 10 to 15 ml per day *(for children)* should be administered once daily in the morning or evening (at mealtime). *For Hepatic encephalopathy*: 30ml once daily in the evening and for the treatment of acute hepatic encephalopathy is 45 to 90 ml divided into 3 doses along with the main meals.

CONTRAINDICATION: It is contra-indicated in patients having appendicitis, galactosemia, intestinal obstruction, unexplained abdominal pain or bleeding and hypersensitivity to the drug or other component of the formulation.

WARNINGS & PRECAUTIONS: It can result in acid-base disturbance and also may cause hypokalemia and hypernatremia. It may lead to accumulation of hydrogen in bowel. Potassium deficiency caused by lactitol may increase the risk of toxic effects of glycosides. Periodic monitoring of serum electrolytes, blood glucose and blood lactate is suggested. If watery stools are noticed, one should either reduce the dose or suspend its administration. Prolonged use of laxatives without interruption should be avoided. Treatment should be begin with the minimum dose, gradually increasing based on the therapeutic response. Care should be taken in patients with lactose intolerance or in diabetic patients.

DRUG INTERACTION: Lactitol can increase the potassium losses caused by other medicines. 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 limit the lactitol's therapeutic efficacy.

ADVERSE REACTIONS: Abdominal distension or cramp, diarrhea, flatulence, abdominal discomfort, nausea, dyspepsia, epigastric pain, urgency of defecation, borborygmi or anal pruritus and vomiting.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)