Only for the use of Medical Professionals



Description

Lacticon[®] is a preparation of Lactitol Monohydrate which is a synthetic disaccharide osmotic laxative and analogue of lactulose. It is derived from lactose consisting of galactose and sorbitol, which is minimally absorbed following oral administration. It has no effect on blood glucose levels and can thus be administered to diabetic patients. It is not hydrolysed by the disaccharides of the gastrointestinal tract and thus reaches the colon unchanged. In the colon, it is broken into short chain low molecular weight organic acids by the intestinal flora which results in an increase in osmotic pressure in the colon, thereby causing an increase in the stool water content and stool volume producing the laxative effect. The mechanism of Lacticon[®] in hepatic encephalopathy is most likely related to the suppression of the absorption of unionized ammonia due to acidification of the contents of the colon. 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.

Indications

 $\textbf{Lacticon}^{\scriptscriptstyle \otimes}$ is indicated for the treatment of constipation and portal systemic encephalopathy.

Dosage and administration

Lacticon[®] should be administered orally. Add one sachet Lacticon[®] granules in a glass of fresh water, mix well and drink immediately. Refill the glass with water and drink again. Lacticon[®] can be mixed with juice, coffee or tea for drinking.

Constipation

Adult: The initial daily dose of **Lacticon®** should be 20 g taken in a single dose with the morning or evening meal and subsequently adjusted to produce one soft stool daily (Then dose of 10 g daily may be sufficient).

Children: The mean dose of Lacticon® is 0.25 g/kg body weight daily.

1 to 6 years: 2.5 - 5 g/day 6 to 12 years: 5 - 10 g/day 12 to 16 years: 10 - 20 g/day

Portal systemic encephalopathy

The dose of **Lacticon®** should be adjusted according to the severity of the patient's disease. The initial recommended dose is 0.5 - 0.7 g/kg body weight daily, divided into three doses with meals and subsequently adjusted to produce two soft stools daily.

Use in pregnancy and lactation

Pregnancy

There is inadequate evidence of safety of lactitol in human pregnancy. Therefore, it should be prescribed only if the potential benefits outweigh the potential risk to the fetus.

Lactation

There have been no studies on the excretion of lactitol into breast milk. It is unlikely that the use of lactitol during breastfeeding would have any clinical effect on the child, because its absorption is minimal. But, this drug should be prescribed only if the potential benefits of the drug outweigh the risks.

Side effects

The common side effects of lactitol are abdominal discomfort such as flatulence, pain, cramps or sensation of fullness. Such effects tend to diminish or disappear after a few days of regular intake of lactitol. Occasionally, nausea or anal pruritus has been reported in some cases.

Contraindications

Lactitol is contraindicated in patients with a known history of hypersensitivity to lactitol or any of its components. It is also contraindicated in patients with appendicitis, galactosemia, and intestinal obstruction.

Warnings and precautions

- Elderly or debilitated patients receiving long term treatment with lactitol should have their serum electrolyte monitored regularly.
- As for all laxatives, pre-existing fluid or electrolyte imbalance should be corrected before starting treatment with lactitol.
- Following treatment of lactitol, hydrogen may accumulate in the bowel. Patients who need to undergo electrocauterization procedure should therefore have a thorough bowel cleansing with a non-fermentable solution.
- · Lactitol is not recommended in case of ileostomy and colostomy.
- · Prolonged use of laxatives without interruption should be avoided.

Drug interactions

Antacid and neomycin should not be given simultaneously with lactitol to cirrhotic patients with portal systemic encephalopathy. Lactitol may increase potassium loss caused by other drugs e.g., thiazide, corticosteroids, carbenoxolone, amphotericin B and it may enhance the risk of toxic effects of glycosides in patients receiving concomitant therapy.

Overdose

The appearance of diarrhea and abdominal cramps is a sign of overdose, and dose reduction may be required. Overdose may cause a shift in serum electrolytes which may require corrective therapy.

Pharmaceutical precautions

Store in a cool (below 25° C) and dry place protected from light. Keep away from the reach of children.

Presentation

Lacticon® granules: Each sachet contains Lactitol Monohydrate BP 10 g.

Packaging quantities

Lacticon[®] granules: Carton of 10 Alu-Alu sachets.

® Registered Trade Mark



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