

Laxitol[®]

Lactitol monohydrate BP
oral solution

DESCRIPTION

Lactitol, known as an "osmotic laxative" is a disaccharide derivative consisting of galactose and sorbitol. It is only minimally absorbed and is not hydrolysed by the disaccharidases of the GIT and thus reaches the colon unchanged. In the colon it is broken down to short chain low molecular weight organic acids by the intestinal flora, resulting in an increase in osmotic pressure in the colon. It thus causes 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. It is absorbed only in minimal amounts. Up to 2% can be found unchanged in the urine.

INDICATIONS

Constipation
Acute and chronic portal systemic encephalopathy.

DOSAGE AND ADMINISTRATION

Constipation
Adult: 15 to 30 ml per day
Paediatric: 2 to 6 years-5ml-10ml per day
For children above age of 6 years: 10 to 15 ml per day
250-400mg/kg body weight per day

The effect of lactitol has been found mostly to occur within a few hours after intake. But in some cases the first laxative response may be delayed until the second or third day of administration. Therefore patients should be advised to maintain an adequate daily fluid intake.

In portal systemic encephalopathy

The dose should be adjusted according to the severity of the patient's disease and their individual response. The initial recommended dose is 0.5 to 0.7g/kg body weight daily, divided into three daily doses with meals and subsequently adjusted to produce 2 soft stools daily.

PRECAUTIONS

Elderly or debilitated patients receiving long-term treatment with lactitol should have their serum electrolytes 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 electrocauterisation procedure should therefore have a thorough bowel cleansing with a

non-fermentable solution.

Lactitol is not recommended in case of ileostomy or colostomy. Prolonged use of laxatives without interruption should be avoided.

PREGNANCY AND LACTATION

Lactitol belongs to pregnancy category B. Animal studies did not reveal any embryotoxic or teratogenic effects. Although the passage of lactitol into breast milk has not been studied, it appears unlikely to have any clinical relevance since it is only minimally absorbed.

SIDE EFFECTS

At the start of the treatment lactitol may produce abdominal discomforts 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.

DRUG INTERACTIONS

Antacids 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 diuretics, corticosteroids, carbenoxolone, amphotericin B and it may enhance the risk of toxic effects of glycosides in patients receiving concomitant therapy.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children.

PACKAGING

- Laxitol[®] 50 ml OS : Each amber pet bottle contains 50 ml oral solution. Each 15 ml contains Lactitol monohydrate BP 10 gm.
- Laxitol[®] 100 ml OS : Each amber pet bottle contains 100 ml oral solution. Each 15 ml contains Lactitol monohydrate BP 10 gm.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

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PM03011 V01