# SINALAX

LACTITOL MONOHYDRATE BP

**Compositions:**
Each sachet contains 10 gm of Lactitol Monohydrate.

**Pharmacology:**
Sinalax is a disaccharide derivatives consisting of galactose and sorbitol, which 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, 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. It is absorbed only in minimal amounts. Up to 2% can be found unchanged in the urine.

**Dosage And Administration:**
Sinalax can be mixed with hot or cold beverages, puddings etc. Dosage will require adjustment to obtaine one daily bowel movement in constipated patients and two daily bowel movements in patients with portal systemic encephalopathy. In constipation Adult: The initial daily dosage should be 20 g taken in a single dose with the morning or evening meal. After a few days, a daily dose of 10 g may be sufficient. Children: The mean dosage is 0.25 g/kg body weight daily. 1to 6 years: 2.5 to 5 g 6 to 12 years: 5 to 10 g 12 to 16 years: 10 to 20 g 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.

**Contraindications:**
Lactitol is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction, galactosemia.

**Warning And Precaution:**
• 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 s of ileostomy or colostomy. • Prolonged use of laxatives without interruption should be avoided.

**Side Effects:**
At the start of the treatment with 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.

**Use in Pregnancy and Lactation:**
Consult doctor before taking LACTITOL MONOHYDRATE if pregnant, doctor will prescribe LACTITOL MONOHYDRATE if the benefits outweigh the risks.It is generally safe to take LACTITOL MONOHYDRATE in breastfeeding. However, consult doctor before

taking LACTITOL MONOHYDRATE if you are breastfeeding, doctor will prescribe you LACTITOL MONOHYDRATE if the benefits outweigh the risks.

**Drug Interaction:**
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.

**Overdosage:**
Please consult your doctor if you have a liver impairment or any concerns regarding this.

**Storage:**
Keep in a cool (below 30°C) and dry place, protected from light. Keep out of the reach of children.

**Packing:**
Sinalax: Box containing 10 sachets of Lactitol Monohydrate. Each sachet contains 10 gm of Lactitol Monohydrate.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.