LACTISOL Syrup 10g/15ml
(L a c t i t o l)

لیکٹیسول ۱۰ گرام/۱۵ ملی لیٹر سیرپ
(لیکٹیولوز)

COMPOSITION:
Each 15ml contains:
Lactitol..... 10g
(Innovator's Specifications)

CHEMICAL FORMULA
C12H24O11

MECHANISM OF ACTION
LACTISOL is a disaccharide derivative consisting of galactose and sorbitol which is only minimally absorbed and is not hydrolyzed by the disaccharidases of the gastrointestinal tract and thus reaches the colon unchanged.
In the colon it is broken down to short chain organic acids, mainly acetic, propionic and butyric add, by the intestinal flora, in particular by the bacteroides and lactobadlli, thus acidifying the contents of the colon, the effect of this acidification reduces the absorption of ammonia. The transformation of lactitol into low molecular weight organic adds results 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
The mechanism of action of lactitol in hepatic encephalopathy is most likely related to suppression of the absorption of unionized ammonia via lowering of colonic pH; 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

DOSAGE AND ADMINISTRATION:
Constipation
LACTISOL syrup should be administered once daily, in the morning or evening, at mealtimes. In some cases, the laxative action may not begin until the 2 to 3 days after the initial dose. Patients should maintain an adequate daily fluid intake
Adults: The usual recommended dose of **LACTISOL** is 15 to 30ml per day
Pediatrics: The usual recommended dose of **LACTISOL** syrup for children in the age group of 2 to 6 years is 10ml per day. For children above age of 6 years the recommended dose is 10 to 15ml per day. The recommended dose for infants or breastfed babies is 5ml per day
Hepatic encephalopathy
For the prevention of hepatic
The usual recommended dose for the treatment of acute phases of hepatic encephalopathy is 45 to 90ml in 3 divided doses along with main meals
For the prevention of hepatic encephalopathy, the recommended dose of **LACTISOL** is 30ml once daily in the evening divided dose

INDICATIONS:
LACTISOL is indicated for treatment of constipation and prevention of hepatic encephalopathy

PHARMACOKINETICS
LACTISOL is not significantly absorbed in the small intestine; only 0.5% to 2% of a dose is partially absorbed as unchanged lactitol. 64% of the dose is 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% or less of a dose)

WARNINGS AND PRECAUTIONS:
Absorption of lactate from colonic metabolism of lactitol can potentially result in acid-base disturbances, and diarrhea induced by lactitol can be associated with hypokalemia and hyperna-tremia. 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 ladate is suggested. If watery stools are noticed, one should either reduce the quantity of administration or suspend administration. As with all laxatives, any pre-existing electrolyte or water balance abnormalities must be corrected. Blood electrolyte levels should be monitored regularly in elderly or debilitated patients on long term treatment. Patients who complain of nausea should be advised to take lactitol with meal.
LACTISOL is not recommended in case of ileostomy or colostomy.
Fecal impaction should be treated by alternative methods prior to using **LACTISOL**.
Following treatment with lactitol hydrogen may accumulate in the bowel. Patients who need to undergo electrocauterization procedures should therefore have a thorough bowel cleansing with a non-fermentable solution

UNDESIRABLE EFFECTS:
Abdominal distension, cramps and flatulence have occurred most frequently (30% to 100% of patients); these effects are most prevalent during the first 10 days of treatment and tend to subside after continued administration. Other less frequent side effects include abdominal discomfort, nausea, dyspepsia, epigastric pain, urgency, or anal pruritus and vomiting in rare cases. Diarrhoea occurs generally with excessive doses of lactitol; but some patients may experience diarrhoea at the recommended dosage. A reduction in dosage with overcome this.

DRUG INTERACTIONS:
LACTISOL can increase the potassium losses caused by other Medicine (e.g. thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B). Potassium deficiency may increase the risk of toxic effects of glycosides in patients receiving concomitant therapy
lactitolcan increase digitalis toxicity. Concomit-antly administration of lactitol with neomycin can cause an increase in neomycin activity
If large spectrum antibacterial agents and ant adds are administered along with lactitol, it can cause a reduction in acidification effed of lactitol on intestinal microflora and consequently limiting therapeutic efficacy
Pregnancy
This drug should be prescribed only if the potential benefits outweigh the potential risk to the fetus
Lactation
Although there have been no studies on the elimination of lactitol in breast milk, it is unlikely that the use of lactitol while breast feeding would have any clinical effect on the child, because its absorption is minimal. But the potential benefits of the drug should outweigh the risks before prescribing this drug

CONTRAINDICATION:
Appendicitis
- Patients with intestinal obstruction, where an underlying organic lesion of the gastrointestinal tract is suspected,
- Hypersensitivity to the drug or any other component of the formulation
- Galactosemia

OVER DOSAGE:
The appearance of diarrhoea and abdominal cramps is a sign of over dosage, dose reduction may be required

HOW SUPPLIED:
LACTISOL Syrup in pack of 120ml

STORAGE & INSTRUCTIONS:
Store between 15-25°C.
Protect from heat, sunlight & moisture.
Keep away from the reach of children.
Shake well before use. For oral use only.
To be sold on prescription of a registered medical practitioner only.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.