LACSYP Syrup (Lactitol monohydrate)

Composition

LACSYP Syrup
Each 15 ml of syrup contains:
Lactitol Monohydrate,USP-NF.....10 g
Benzoic Acid, IP.....0.0225 g
(as preservative)

Dosage Form

Syrup

Pharmacology

Pharmacodynamics

Lactitol is a synthetic, lactulose-like disaccharide. It is derived from lactose and is minimally absorbed following oral administration. It is more palatable, better tolerated and produces a more predictable cathartic activity than lactulose. Lactitol has calorific value of 2 kcal/g (8.5 KJ/g) and has no effect on blood glucose levels. It can, therefore, be given to diabetes patients.

Mechanism of Action
Lactitol is a disaccharide derivative consisting of galactose and sorbitol, which is only minimally absorbed and is not hydrolysed by the disaccharidases of the gastrointestinal tract and, thus, reaches the colon unchanged. In the colon, it is broken down into short-chain organic acids, mainly acetic, propionic and butyric acid, by the intestinal flora, in particular by the bacteroides and lactobacilli, 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 acid 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 affect.

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 faecal nitrogen excretion and decreases intestinal transit time, with a reduction in the time for production and absorption and other potential toxins.

Pharmacokinetics

Lactitol is not significantly absorbed in the small intestine; only 0.5% to 2% of a dose is partially absorbed as unchanged lactitol. While 64% of the dose is absorbed by the colonic mucosa as volatile fatty acids, 6.5% is excreted in the faeces. Small amounts of unchanged lactitol appear in the urine (2% or less of a dose)

Indications

LACSYP syrup is indicated for the treatment of constipation and the prevention of hepatic encephalopathy.

Dosage and Administration

Constipation

LACSYP syrup should be administered once daily, in the morning or evening, at mealtimes. In some cases, the laxative action may not begin until the second or third day after the initial dose. Patients should maintain an adequate daily fluid intake.

Adults
The usual recommended dose of **LACSYP** syrup is 15 to 30 ml per day.

Paediatric
The usual recommended dose of **LACSYP** syrup for children in the age group of 2 to 6 years is 10 ml per day. For children above the age of 6 years, the recommended dose is 10 to 15 ml per day. The recommended dose for infants or breastfed babies is 5 ml per day.

Hepatic Encephalopathy

Adults
For the prevention of hepatic encephalopathy, the recommended dose of **LACSYP** syrup is 30 ml once daily in the evening.

The usual recommended dose for the treatment of the acute phase of hepatic encephalopathy is 45 to 90 ml in three divided doses along with main meals.

Paediatric
The mean dosage is 0.25 g/kg body weight daily.
Aged 1 to 6 years: 2.5 to 5 g per day
Aged 6 to 12 years: 5 to 10 g per day
Aged 12 to 16 years: 10 to 20 g per day

For taking fraction doses (e.g. 2.5 or 5 g) of presented 10g of lactitol, the whole 10 g should be dissolved in water. Half of the solution (5g) and one-fourth (2.5 g), respectively, should be taken. The rest of the solution should be discarded.

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.

Portal Systemic Encephalopathy

The dose should be adjusted according to the severity of the patient's disease and his or her individual response.

The initial recommended dose is 0.5 to 0.7 g/kg body weight daily, divided into three daily doses with meals and subsequently adjusted to produce two soft stools daily.

OR

As directed by the physician.

Contraindications

Appendicitis

- Patients with intestinal obstruction, where an underlying organic lesion of the gastrointestinal tract is suspected, or in cases of unexplained abdominal pain or bleeding.
- Hypersensitivity to the drug or any other component of the formulation.
- Galactosaemia.

Warnings and Precautions

Absorption of lactate from the colonic metabolism of lactitol can potentially result in acid-base disturbances, and diarrhoea induced by lactitol can be associated with hypokalaemia and hypernatraemia. Potassium deficiency may increase the risk of the toxic effects of glycosides in patients receiving concomitant therapy.

Periodic monitoring of serum electrolytes, blood glucose and blood lactate 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 meals.

Lactitol is not recommended in case of ileostomy or colostomy. Facial impaction should be treated by alternative methods prior to using lactitol.

Following treatment with lactitol, hydrogen may accumulate in the bowel. Patients who need to undergo electro cauterization procedures should, therefore, have a thorough bowel cleansing with a non-fermentable solution.

Drug Interactions

Lactitol can increase the potassium losses caused by other medicines (e.g. thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B). Potassium deficiency may increase the risk of the toxic effects of glycosides in patients receiving concomitant therapy.

Lactitol can increase digitalis toxicity. Concomitant administration of lactitol with neomycin can cause an increase in neomycins activity.

If broad-spectrum antibacterial agents and antacids are administered along with lactitol, it can cause a reduction in the acidification effect of lactitol on the intestinal microflora and, consequently, limit therapeutic efficacy.

Pregnancy

This drug should be prescribed only if the potential benefits outweigh the potential risk to the

foetus.

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.

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. Generally, diarrhoea occurs with excessive doses of lactitol; but, some patients may experience diarrhoea at the recommended dosage. A reduction in dosage will overcome this.

Overdosage

The appearance of diarrhoea and abdominal cramps is a sign of overdosage, and dose reduction may be required.

Storage and Handling Instructions

Store in a cool, dry place.

Packaging Information

LACSYP: Bottle of 200 ml syrup

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