15-07-2022
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210mm

LACASIL® Syrup / Sachet
(Lactitol Monohydrate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

LACASIL® Syrup
Each 15ml contains:
Lactitol Monohydrate USP 10g

LACASIL® 10g Sachet
Each sachet contains:
Lactitol Monohydrate USP 10g

PHARMACEUTICAL FORM
Syrup
Crystalline powder for oral solution in sachet.

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS:
- Symptomatic treatment of constipation.
- Hepatic encephalopathy.

POSOLOGY AND METHOD OF ADMINISTRATION:
Syrup:
Constipation: Should be administered once daily, in the morning or evening, at mealtimes. In some cases, the laxative action may not begin until the 2nd or 3rd day after the initial dose. Patients should maintain an adequate daily fluid intake.

Adults: The usual recommended dose is 15 to 30ml per day.

Paediatrics:
Infants or breastfed babies: The recommended dose is 5ml per day.
Children in the age group of 2 to 6 years: The usual recommended dose is 10ml per day.
Children above age of 6 years: The recommended dose is 10 to 15ml per day.

Hepatic Encephalopathy:
Adults: For the prevention of hepatic encephalopathy, the recommended dose is 30ml once daily in the evening.
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.

OR
As directed by the physician.

Sachet:
Constipation:
Adult: The initial daily dosage should be 20g (2 sachets) taken in a single dose with the morning or evening meal and subsequently adjusted to produce 1 soft stool daily (dose of 10g daily may be sufficient).

Infant and Children:
- Infant from 0 to 12 months: 2.5g per day.
- 1 to 6 years: 5g per day, in a single dose.
- 7 to 14 years: 10g (1 sachet) per day, in a single dose.

Pour the contents of one or two unit-dose packets, as prescribed, into an empty 8-ounce glass.
Add 4 ounces to 8 ounces of water to the glass containing the powder and stir thoroughly to dissolve.
Drink the entire contents of the glass. **OR**
Can be mixed and used with any soft food.

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.

Hepatic encephalopathy:
The ideal dose is one that subsequently leads to two stools a day. The duration of treatment varies according to the symptoms of the patients:
- In case of coma or pre-coma: 4 to 8 sachets diluted into water.
- Follow-up treatment: 1 to 2 sachets, 3 times a day.
- **To get the 40% solution:** Dissolve 200g into 200ml hot water with constant stirring. After dissolution, add 168ml of cool water. This solution may be administered, in case of acute attack at a dose of 1 to 2ml/kg/day (i.e., 0.4 to 0.8g/kg/day).

OR
As directed by the physician

CONTRAINDICATIONS:
- Hypersensitivity to the active substance.
- Inflammatory colon disease (Ulcerative colitis, Crohn's disease).
- Occlusive or subocclusive syndrome.
- Digestive perforation or suspicion of perforation.
- Abdominal pain syndromes of undetermined cause.
- Galactose-free diet due to the presence in the powder of this related sugar (8%):
  - In breastfed infants.
  - In children with an autosomal recessive hereditary intolerance to fructose.
  - In case of galactosemia (incomplete metabolism of lactitol can lead to the development of fructosemia and galactosemia with sequelae).
- Pre-existing water-electrolyte imbalance.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Prolonged use in the treatment of constipation is not recommended.

Drug treatment of constipation is only an adjunct to lifestyle and dietary treatment:
- Enrichment of the diet with vegetable fibers and drinks.
- Physical activity counselling and re-education of the exemption.

In infants and young children, the use of lactitol is possible on medical recommendation.
The use of lactitol is not recommended in patients with fructose or galactose intolerance, galactosemia or glucose-galactose malabsorption syndrome or lactase deficiency.
Diarrhoea which may be induced by lactitol can lead to disturbances of the hydro-electrolyte balance: this medicinal product should therefore be used with caution in patients prone to presenting hydro-electrolyte disturbances.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
Laxatives should not be taken at the same time as other medications, after taking a medication, wait at least 2 hours before taking a laxative. Lactitol can increase the potassium losses caused by other medicines (e.g., thiazide

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diuretics, corticosteroids, carbenoxolone, amphotericin B). Lactitol can increase digitalis toxicity. Concomitant administration of lactitol with neomycin can cause an increase in neomycin's activity. If large spectrum antibacterial agents and antacids are administered along with lactitol, it can cause a reduction in acidification effect of lactitol on intestinal microflora and consequently limiting therapeutic efficacy.

FERTILITY, PREGNANCY AND LACTATION:
There are no reliable data on teratogenesis in animals.
There are currently no relevant or sufficient data to assess a possible malformative or foetotoxic effect of lactitol when administered during pregnancy.
However, given the lack of absorption, no effects are expected during pregnancy and lactation, therefore lactitol can be used during pregnancy and lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
No known influence on the ability to drive or use non-purpose machines.

UNDESIRABLE EFFECTS:
- At the beginning of treatment, lactitol can cause abdominal discomfort, such as flatulence and, although rarely, abdominal pain or sometimes a bloating sensation. Such effects tend to diminish or disappear after a few days of treatment with lactitol.
- Due to inter-individual differences, some patients, even when taking the recommended dose, may suffer from diarrhoea. A reduction in dosage will solve this problem.

Systematic Class / Frequency	Side effects
Gastrointestinal disorders	
Rare	Abdominal pain, bloating, diarrhoea, flatulence, vomiting.
Very rare	Nausea, gastrointestinal abnormalities, anal pruritus.

OVERDOSE:
Discontinuation of therapy or reduction of dosage. Correction of possible hydro-electrolyte disorders in the event of significant fluid loss secondary to diarrhoea.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Hypoammonemic osmotic laxative. **ATC code:** A06AD12.

Lactitol causes an increase in osmotic pressure, promoting stool hydration and an increase in intestinal peristalsis. In the colon, the transformation of lactitol into organic acids lowers the pH of the colonic contents, thus reducing the absorption of ammonia.

Mechanism of action:
Lactitol is a disaccharide derivative consisting of galactose and sorbitol which is only minimally absorbed and is not hydrolyzed by the disaccharides 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 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 acids 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

PHARMACOKINETIC PROPERTIES:
Lactitol, a synthetic disaccharide, crosses the upper parts of the digestive tract unchanged and without resorption. At the level of the colon, under the effect of the local saccharolytic flora, it is transformed into organic acids (lactic and acetic), which are eliminated in the stools.

SHELF LIFE
See expiry on the pack

AVAILABILITY
LACASIL® syrup in a pack of 120ml
LACASIL® 10g sachet in a pack of 8's

INSTRUCTIONS
Dosage: As advised by the physician.
To be sold on the prescription of a registered medical practitioner only.
Keep out of reach of children.
Avoid exposure to heat, light, humidity and freezing.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.

Medicine should not be used if container is leaking or it contains undissolved particle(s).

لیکاسِل® سیرپ / ساشے

(لیکٹیٹول مونو ہائیڈریٹ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو گرمی، روشنی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔
دوا کے لیک ہونے یا اس میں کوئی غیر حل پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
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