

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Torbulk

(Lactitol Monohydrate and Ispaghula Husk Powder)

COMPOSITION

Each 15 g powder contains :

Lactitol Monohydrate U.S.P. 10 g

Ispaghula Husk I.P. 3.5 g

Excipients q.s.

Colours : Sunset Yellow FCF & Ponceau 4 R

Orange Lemon flavoured

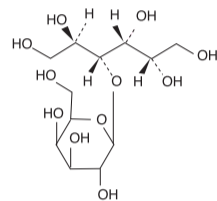
DESCRIPTION :

Lactitol

Lactitol is a white or light brown, odorless crystal. Has a mild, sweet taste, and no aftertaste.

Chemical Name of Lactitol is 4-O-β-D-Galactopyranosyl - D-glucitol Monohydrate and a Molecular formula is C₁₂H₂₄O₁₁.H₂O.

Molecular weight is : 362.34.



Ispaghula Husk

Pale buff, brittle flakes, more or less lanceolate, up to 2 mm long and 1mm wide at the center, much broken into smaller fragments; many of the flakes having a small, brownish, oval spot, about 0.8 to 1.0mm long, in the center; the material swells rapidly in water, forming a stiff mucilage.

Dosage Form : Powder

CLINICAL PHARMACOLOGY

Pharmacodynamics

Lactitol

Lactitol is a disaccharide composed of galactose and sorbitol, which is not hydrolyzed by disaccharidases in the small intestine. Because of this substance passes through the small intestine with only minimally absorbed and reaches the colon unchanged.

In colon Lactitol metabolized by intestinal flora, especially Bacteroides and Lactobacilli, mainly to acetate, propionate and butyrate. Conversion of Lactitol to short-chain organic acids increases the osmotic pressure in the colon contents, increasing stool water content and volume, giving rise to the laxative effect. The beneficial effect of Lactitol of hepatic encephalopathy is considered to be related to

the greatly increased production of acidic products in the large intestine, where Lactitol is administered in high doses. It is not clear whether the reduction of ammonia in the blood due to a decreased production, decreased absorption or increased elimination.

Lactitol has a negligible caloric content (2 kcal / g or 8.5 kjoule/g) and has no effect on insulin levels in serum or blood glucose levels and can therefore be used in patients with diabetes.

Ispaghula Husk

The active constituent, ispaghula husk, is the epidermis and collapsed adjacent layers removed from the dried ripe seeds of *plantago ovata*, containing mucilage and hemicelluloses.

The ispaghula husk is not absorbed and produces its effect as a bulking agent by physical means alone. It is capable of absorbing up to 40 times its own weight in water *in vitro*, and part of its activity can be attributed to its action as a simple bulking agent. In addition, colonic bacteria are believed to use the hydrated material as a metabolic substrate. This results in an increase in the bacterial cell mass with consequent softening of the faeces.

Pharmacokinetic

Lactitol

Lactitol passes through the small intestine with very low absorption and reaches the colon unchanged. It exerts its effects in the colon lumen, where it has a bioavailability of almost 100%. Less than 2% is excreted in the urine in unchanged form.

Ispaghula Husk

The mode of action of ispaghula husk is physical and does not depend on absorption into the systemic circulation.

INDICATION

For the treatment of chronic idiopathic constipation in adult patients only

CONTRAINDICATIONS

- Appendicitis
- Patient's with intestinal obstruction, where an underlying organic lesion of the gastrointestinal tract is suspected, or in cases of unexplained abdominal pain or bleeding
- Galactosemia
- Not to be given to patients with faecal impaction, colonic atony
- Hypersensitivity to ispaghula, lactitol or any of the ingredients.

WARNINGS AND PRECAUTIONS

Prolonged use of laxatives without ceasing to be avoided. Cases of chronic constipation should always be treated with high-fiber diet, adequate fluid intake or physical activity.

It is important to take the product with sufficient fluid a liquid suspension and drunk immediately after mixing. The last dose should not be taken immediately before going to sleep since impaired or reduced gastric

motility may impair the intestinal passage and then cause sub-obstruction. It may be advisable to supervise treatment in the elderly or debilitated and patients with intestinal narrowing or decreased motility, as rare instances of gastrointestinal obstruction have been reported with mucilloid preparations when taken, contrary to the administration instructions, with insufficient liquid.

After treatment with Lactitol, hydrogen may accumulate in the intestine. Patients who require treatment with diathermy or other similar electronic means shall be subjected to thorough bowel cleansing with a non-fermentable solution before surgery.

Diarrhoea, which was brought about by an overdose can cause electrolyte imbalance and for this reason, the optimal dose determined at the beginning of therapy resulting in a daily bowel movement in patients with constipation. Elderly or mentally disabled patients who are receiving long-term Lactitol should be checked periodically for serum electrolytes. As with any type of laxative is fluid and electrolyte abnormalities corrected prior to treatment.

The drug may cause allergic reactions in people sensitive to inhaled or ingested ispaghula powder. The colouring agent, Sunset Yellow FCF, can cause allergic type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

If symptoms persist consult your doctor.

Patients who suffer from nausea are recommended to take the product in water with meal.

Lactitol is not recommended for patients with ileostomy or colostomy.

DRUG INTERACTION

Like all other laxatives, Lactitol can increase potassium loss caused by other drugs (eg. Thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B). Potassium deficiency may increase the risk of toxic effects of glycosides in patients receiving concomitant treatment with such drugs.

ADVERSE EFFECTS

Ispaghula Husk

Gastrointestinal disorders :

Ispaghula as with other bulk laxatives, may temporarily increase flatulence and abdominal distension when the product is first used. Other symptoms including nausea, diarrhoea and abdominal discomfort or pain have rarely been reported (<1 in 1000).

Intestinal obstruction and faecal impaction may occur very rarely (<1 in 10,000), especially if the product is taken with insufficient fluid.

Immune system disorders:

There are very rare reports (<1 in 10,000) of allergic or hypersensitivity reactions associated with the ingestion or inhalation of Ispaghula including skin rashes or allergic dermatitis, rhinitis, urticaria, bronchospasm and anaphylactic reactions.

Lactitol

The most common side effect is gastrointestinal disturbances that occur in approximately 25% of patients.

Common (> 1 / 100)

GI: meteorism, flatulence, abdominal pain, cramps, Diarrhoea, feeling full

Less ordinary (1 / 100 -1/1000)

GI: Borborygmi, nausea, anal itching.

Rare (1 / 1000 - 1 / 10000)

GI: Vomiting.

The side effects are usually transient and disappear after a few days of regular use.

OVERDOSAGE

No instances of true overdosage have been reported. If overdosage should occur there is no specific treatment and symptomatic measures should be employed.

Diarrhoea is a sign of overdose and can be remedied by dose reduction. Diarrhoea can also cause changes in serum electrolytes that can be corrected.

DOSAGES AND ADMINISTRATION

Because of differences in efficacy between patients, the dose should be individualized until daily bowel movement is achieved.

Adults (including elderly): 15 g powder (about one measure spoon) once or twice daily or as directed by the Physician.

Add one measure spoon full of Torbulk to a glass of water (approx. 150 ml). Stir briskly and consume the contents immediately. Follow it up with a glass of water. Adequate fluid intake should be maintained.

The laxative effect occur usually within a few hours after ingestion, but can take up to two to three days.

USE IN PREGNANCY, NURSING MOTHER, USE IN CHILDREN AND OLDER PATIENTS

Ispaghula

Controlled studies in pregnant and lactating women are not available, but the product has been in wide use for many years without apparent ill consequence and animal studies have shown no hazard. Ispaghula is not thought to be absorbed nor is it thought to enter breast milk. Nevertheless the benefits of therapy should be weighed against the possible risks if used during pregnancy and lactation.

Lactitol

Pregnancy Category B: 1.

Experience of Lactitol to pregnant women is limited. Animal studies have shown no teratogenicity, but Lactitol should be used during the first trimester of pregnancy and breast-feeding only when absolutely necessary.

Breastfeeding Group IVb.

Lactitol should be used during breast-feeding only when absolutely necessary.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store at a temperature below 30°C.

Protect from moisture. Keep out of reach of children.

Replace the lid tightly after use.

PRESENTATION

Torbulk is available as 90 g HDPE container.



Marketed by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Manufactured by :
Tirupati Medicare Ltd.
Nahan Road, Paonta Sahib,
Distt. Sirmour - 173 025 (H.P.)