

TORBULK

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

Abbreviated Prescribing information for TORBULK [Lactitol Monohydrate & Ispaghula Husk Powder]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Lactitol*: 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. *Ispaghula Husk*: 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.

INDICATIONS: For the treatment of chronic idiopathic constipation in adult patients only.

DOSAGE AND ADMINISTRATION: As directed by the Physician. 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.

CONTRAINDICATION: *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 & 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.. 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. Lactitol is not recommended for patients with ileostomy or colostomy.

DRUG INTERACTIONS: 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 REACTIONS: 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. Intestinal obstruction and faecal impaction may occur very rarely especially if the product is taken with insufficient fluid. There are very rare reports of allergic or hypersensitivity reaction associated with the ingestion or inhalation of Ispaghula including skin rashes or allergic dermatitis, rhinitis, urticaria, bronchospasm and anaphylactic reactions. **Lactitol:** *GI*: meteorism, flatulence, abdominal pain, cramps, Diarrhoea, feeling full, Borborygmi, nausea, anal itching, and Vomiting.

MARKETED BY:

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(Additional information is available on request)