

UNILAX ORAL SOLUTION.

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

Abbreviated Prescribing information for UNILAX ORAL SOLUTION. (Lactulose Solution U.S.P.)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Lactulose is a synthetic disaccharide derivative of lactose that consists of one molecule of galactose and one molecule of fructose. Saccharolytic bacteria present in the large intestine subsequently break the substance down into organic acids like lactic acid and small amounts of formic and acetic acids. Such resultant volatile fatty acid metabolites, in combination with hydrogen and methane that is also generated consequently enhance intraluminal gas formation, peristaltic gut motility, and elicit an osmotic effect that facilitates an increase in the water content of stool as well as associated stool softening.

INDICATION: It is indicated for, (1) For the treatment of constipation, (2) Intestine preparation before any surgery and (3) For the treatment of hepatic encephalopathy.

DOSAGE AND ADMINISTRATION: Lactulose can be taken diluted or undiluted, ideally in one go and at the same time daily, such as during breakfast. Dosage should be individualized, and patients should drink 1.5–2 liters of fluid daily; a measuring cup may be used for dosing. *Dosing in constipation:* Lactulose can be taken once daily or in two doses, with dosage adjusted after a few days based on response. Typical daily doses range from 15–45 ml for adults to up to 5 ml for infants; bottles with measuring cups are recommended for precise dosing, especially in young children. For adults with HE, start with 30–45 ml lactulose 3–4 times daily, adjusting to achieve 2–3 soft stools per day. Use in children is not established, and no special dosing is needed for elderly or those with renal/hepatic issues.

CONTRAINDICATION: Hypersensitivity to any of the components of the product., Use in patients with galactosaemia. (Patients who require a low galactose diet), Acute inflammatory bowel disease (ulcerative colitis, Crohn's disease), gastrointestinal obstruction or subocclusive syndromes, digestive perforation or risk of digestive perforation, painful abdominal syndromes of undetermined cause.

WARNINGS & PRECAUTIONS: Lactulose should be used cautiously in patients with sugar intolerances, Roemheld syndrome, or lactose intolerance, and may cause bloating or diarrhea. Diabetics can generally use standard doses without concern. Long-term use, especially in the elderly or unwell, requires electrolyte monitoring. Use in children should be rare and medically supervised; adequate fluid intake is important during treatment.

DRUG INTERACTION: Lactulose may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency. With increasing dosage, a decrease of pH-value in the colon is found. Therefore, drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.

ADVERSE REACTIONS: Diarrhoea, Flatulence, Abdominal pain, Nausea, Vomiting, Electrolyte imbalance due to diarrhoea.

MANUFACTURED BY:

TORRENT
PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/ UNILAX ORAL SOLUTION/MAR 2026/01/ABPI

(Additional information is available on request)