160 mm x 210 mm

Osmolax Solution (Lactulose USP 0.67g/ml)

Product Name:
Osmolax Solution (Lactulose USP 0.67 G/ML)
Name and Strength of Active Ingredient(s):
Lactulose 100ml
EACH ML CONTAINS LACTULOSE USP 0.67 GM AS LACTULOSE CONCENTRATE USP
Product Description:
A clear, colorless to brownish yellow, flavored viscous liquid, filled and sealed in amber color PET bottle with SQUARE printed white color cap.
Pharmacodynamics:
Pharmacology: In the colon, lactulose is broken down by colonic bacteria into low molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of the colonic contents. These effects stimulate the peristalsis of the colon and normalize the consistency of the stools. The constipation is cleared and the physiological rhythm of the colon is reinstated. In portal systemic encephalopathy (PSE) c.q. (pre) coma hepaticum, the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (eg, lactobacillus), trapping of ammonia in the ionic form by the acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis. Within this context, however, it should be realized that hyperammonia alone cannot explain the neuropsychiatric manifestations of PSE. The ammonia however might serve as a model compound for other nitrogenous substances.
Pharmacokinetics:
Pharmacokinetics: Lactulose is scantily absorbed after oral administration. Not being absorbed as such, it reaches the colon unchanged. There, it is metabolized by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g (40-75 mL): At higher dosages, a part may be excreted unchanged.
Indication:
• Constipation: regulation of the colonic physiological rhythm
• When soft stool is considered of medical benefit (haemorrhoids, post colonic/anal surgery)
• Hepatic encephalopathy (HE): treatment and prevention of hepatic coma or precoma
Recommended Dose:
Dosing in Constipation or where soft stool is considered of medical benefit:
Osmolax may be given as a single daily dose or in two divided doses.
After a few days, the starting dosage may be adjusted to the maintenance dose based upon treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

	Starting Dose	Maintenance Dose Daily
Adults and Adolescents	15-45ml	15-30ml
Children (7-14 years)	15ml	10-15ml
Children (1-6 years)	5-10ml	5-10ml
Infants under 1 year	up to 5 ml	up to 5ml

Dosing in Hepatic Encephalopathy (for adults only):
Starting dose: 3 to 4 times daily, 30-45ml.
This dose may be adjusted to the maintenance dose to achieve two or three soft stools each day.
Paediatric Population:
The safety and efficacy in children (newborn to 18 years of age) with HE have not been established.
Elderly Patients and Patients with Renal or Hepatic Insufficiency:
No special dosage recommendations as systemic exposure to lactulose is negligible.
Route of Administration: Oral
Contraindication: Galactosaemia, bowel obstruction, hypersensitivity to any of the components of Osmolax
Warning and Precaution:
Should the constipation not react to treatment after a couple of days or reoccur after treatment, then a physician should be consulted. If used by patients suffering from galactosaemia or lactase deficiency, then the amount of related sugars should be taken into consideration.
The dose normally used in constipation should not pose a problem for diabetics. The dosage in the treatment of (pre) coma hepaticum is usually much higher and may pose a problem for diabetics.
Interactions with Other Medicaments: None known.
Incompatibilities:
Due to lactulose's mode of action of lowering the pH in the colon, drugs that have a colon pH-dependent release (eg, 5-acetylsalicylic acid agents) may be inactivated.
Pregnancy and Lactation:
Lactulose may, on the basis of current knowledge, be safely used as instructed during pregnancy and lactation.
Side Effects:
Flatulence may occur during the first few days of treatment. As a rule, it disappears after a couple of days. When dosages higher than instructed are used, belly ache and diarrhoea may occur. In such case, the dosage should be decreased. If high doses (normally only associated with PSE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea.
Symptoms and Treatment of Overdose:
No data on cases of overdosing are available. If dosed too high, both headache and diarrhea can occur. In such instance, cessation of treatment will normally suffice.
Effects on the Ability to Drive or Operate Machinery:
When taken as prescribed, Osmolax does not influence the ability to drive or operate machines.
Storage Condition:
Store below 30°C. Protect from light.
Dosage Form and Packaging Available:
ORAL LIQUIDS in form of ORAL SOLUTION; 100ml oral solution in PET amber bottle.

Manufactured by:
SQUARE PHARMACEUTICALS PLC.
Square Road, Salgaria, Pabna 6600, Bangladesh.

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