Open Size : 150 x 220 mm

TOTALAX
(Lactulose Solution USP 667 mg/ml)

NAME OF MEDICINAL PRODUCT
TOTALAX (Lactulose Solution USP 667 mg/ml)

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains Lactulose (As Lactulose concentrate USP) 667 mg
Product contains Lactose.

PHARMACEUTICAL FORMS
Oral solution
Colourless to amber syrupy liquid filled in white PET bottle.

CLINICAL PARTICULARS

Therapeutic Indications
• 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

Posology and method of administration

Posology
The lactulose solution may be administered diluted or undiluted. Each dose may if necessary be taken with water or fruit juices, etc. Each dose of lactulose should be swallowed in one and should not be kept in the mouth for an extended period of time. The posology should be adjusted according to the individual needs of the patient.
In case of single daily dose, this should be taken at the same time, e.g. during breakfast.
During the therapy with laxatives it is recommended to drink suffcient amounts of fluids (1.5–2 litres, equal to 6-8 glasses) during the day.
Dosing in constipation:
Lactulose 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.
Lactulose oral solution in bottles:

	Starting dose daily	Maintenance dose daily
Adults and adolescents	15-45 ml,	15-30 ml,
Children (7-14 years)	15 ml,	10-15 ml,
Children (1-6 years)	5-10 ml	5-10 ml
Infants under 1 year	up to 5 ml	up to 5 ml

Dosing in Hepatic Encephalopathy
Adults
Starting dose: 3 to 4 times daily 30-45 ml (6-9 x 5 ml spoonfuls). This dose may be adjusted to the maintenance dose to achieve two or three soft stools each day.
Method of Administration
Oral use
For lactulose in bottles the measuring cup may be used.
Special populations
Paediatric population
The safety and efficacy in children (newborn to 18 years of age) with HE have not been established. No data are available.
Elderly patients and patients with renal or hepatic insuffciency
No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Contraindications
● If you are hypersensitive (allergic) to lactose or to any of the ingredients of Totalax oral solution.
● if you suffer from galactosaemia.
● if you suffer from gastrointestinal obstruction, digestive perforation or risk of digestive perforation.

Special Warnings and Precautions for use
Painful abdominal symptoms of undetermined cause should be evaluated to exclude undiagnosed perforation or obstruction or undiagnosed disease/condition that predisposes to either before the treatment is started.
In case of insuffcient therapeutic effect after several days the dose and/or additional measures should be re-considered.
Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.
It should be taken into account that the defaecation reflex could be disturbed during the treatment.
The dose normally used in constipation should not pose a problem for diabetics.
The dose used in the treatment of HE is usually much higher and may need to be taken into consideration for diabetics.
This product contains lactose, galactose and small amounts of fructose. Therefore, patients with the rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.

Paediatric population
Use of laxatives in children should be exceptional and under medical supervision

Interaction with other medicinal products and other forms of interaction
None known

Fertility, Pregnancy and Lactation
Fertility
No effects are to be expected, since systemic exposure to lactulose is negligible.
Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.
Lactulose solution can be used during pregnancy.
Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to lactulose is negligible.
Lactulose can be used during breast-feeding.

Effect on ability to drive and use machines
Lactulose has no or negligible influence on the ability to drive and use machines.

Undesirable 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, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased. See also overdose.
If high doses (normally only associated with hepatic encephalopathy, HE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea. Dosage should then be adjusted to obtain two or three formed stools per day.
Hypersensitivity reactions mainly limited to the skin have been observed and identified as potential adverse reactions during postapproval use. Because these reactions were reported spontaneously from a population of uncertain size, it is not possible to reliably estimate their frequency*.
Tabulated list of adverse reactions
The following undesirable effects have been experienced with the below indicated frequencies in lactulose-treated patients in placebo-controlled clinical trials:
Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000).

System/organ class	Frequency category			
	Very Common	Common	Uncommon	*Frequency not known
Immune system disorder				Hypersensitivity
Gastrointestinal disorders	Diarrhoea	Flatulence, abdominal pain, nausea, vomiting		
Skin and subcutaneous tissue disorders				Rash, pruritus, urticarial, erythema
Investigations			Electrolyte imbalance due to diarrhoea	

Paediatric population
The safety profile in children is expected to be similar as in adults.

Overdose
If the dose is too high, the following may occur:
Symptom: diarrhoea, loss of electrolytes and abdominal pain.
Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances.
No specific antidote. Symptomatic treatment should be given.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics Properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC code: A06A D11
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 colonic contents. These effects stimulate peristalsis of the colon and return the consistency of the stool. The constipation is cleared and the physiological rhythm of the colon is reinstated.
In hepatic encephalopathy (HE) the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by 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.

Pharmacokinetics Properties
Lactulose is poorly absorbed after oral administration and it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged.

PHARMACEUTICAL PARTICULARS

List of Excipients:
None

Incompatibilities
None known

Shelf Life
36 months from the date of manufacture.

Special Precautions for Storage
Do not store above 30ºC.

Nature and Contents of Container
200 ml PET Bottle with measuring cup.

Special Precautions for Disposal
No special requirements.

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