MODULE -1
ADMINISTRATIVE INFORMATION FOR LACTULIN SOLUTION

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Lactulin Solution

2. QUALITATIVE QUANTITATIVE FORMULA

ITEM	DRUG NAME	SCALE PER 15 ML	STD QTY PER 1000 ML	FUNCTIONS
1	Lactulose Use: Lactulose Concentrate USP	10 g (15 ml)*	 1000.000 mL	Active
2	Riboflavin BP	0.6 mg*	0.040 g	Colorant
3	Orange Oil (5 Folds Extract)	0.0225 ml*[1] (0.01928 mg)*	1.500 mL (1.285 g)	Flavoring agent

Notes:

* Quantities not to be disclosed. For Company information only.

[1] wt/ml @ 0.857 g/mL (Range: 0.850 g/mL – 0.865 g/mL).

MODULE -1
ADMINISTRATIVE INFORMATION FOR LACTULIN SOLUTION

3. PHARMACEUTICAL FORM
Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
For the relief of occasional constipation and of chronic portal hypertension and hepatic encephalopathy.

4.2 Posology and method of administration
As directed by Physician

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed
Use in patients with galactosaemia.
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.

4.4 Special warnings and precautions for use
In case of insufficient therapeutic effect after several days consultation of a physician is advised.
From the route of synthesis Lactulin may contain small amounts of sugars
(Not more than 67 mg/ml lactose, 100 mg/ml galactose, 67 mg/ml epilactose, 27 mg/ml tagatose and 7 mg/ml fructose).
Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose mal-absorption should not take this medicine.
Lactulose should be administered with care to patients who are intolerant to lactose.
Lactulose may contain more than 5 g lactose/galactose/epilactose depending upon the dose taken. This should be taken into account in patients with diabetes mellitus.15 ml of Lactulose contain 42.7 KJ (10.2 kcals) = 0.21 BU.
For patients with gastro-cardiac syndrome (Roemheld syndrome) lactulose should only be taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after lactulose intake, the dose should be reduced or the treatment should be discontinued.
Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.
For elderly patients or patients that are in bad general condition and take lactulose for a more than 6 months period, periodic control of electrolytes is indicated.
During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5-2 l/day, equal to 6-8 glasses).
Paediatric population
Use of laxatives in children should be exceptional and under medical supervision.

MODULE -1
ADMINISTRATIVE INFORMATION FOR LACTULIN SOLUTION

Lactulose should be administrated with caution in infants and small children with autosomal recessive hereditary fructose intolerance.
The defecation reflex may be altered during the treatment with lactulose.

4.5 Fertility, pregnancy and lactation

Pregnancy

Limited data on pregnant patients indicate neither malformative nor foeto/neonatal toxicity. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).

The use of Lactulin may be considered during pregnancy if necessary.

Breast-feeding

Lactulin can be used during breastfeeding

4.6 Effects on ability to drive and use machines
None

4.7 Overdose
If the dose is too high, the following may occur: diarrhoea and abdominal pain.

MODULE -1
ADMINISTRATIVE INFORMATION FOR LACTULIN SOLUTION

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for constipation. Osmotically acting laxatives.

ATC code: A06A D11

Lactulose is a synthetic disaccharide formed from D-galactose and fructose. Lactulose as a prebiotic substance strengthens the growth of bifidobacteria and lactobacilli, whereas Clostridium and Escherichia coli may be suppressed.

In the colon lactulose is metabolised by bacterial enzymes to short chain fatty acids mainly lactic and acetic acid as well as methane and hydrogen. This effect leads to a decrease of the pH-value and an increase of the osmotic pressure in the colon. This causes stimulation of peristalsis and an increase of the water content of the faeces.

5.2 Pharmacokinetic properties

Lactulose is practically not absorbed, because in man there is no corresponding disaccharidase available in the upper intestinal tract. Not being absorbed as such, 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.

6. Pharmaceutical particulars

6.1 List of excipients

Riboflavin BP

Orange Oil (5 Folds Extract) MS

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C, at a dry place. Protect from light.

MODULE -1
ADMINISTRATIVE INFORMATION FOR LACTULIN SOLUTION

Keep medicines out of reach of children