1.4.1 PRESCRIBING INFORAMTION (SPC)
1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT
Proprietary Name
LACTITOSS SOLUTION

Approved Generic Name
Lactulose Solution USP

1.1 Strength
Each 15 ml contains:
Lactulose Concentrate USP equivalent to Lactulose 10 gm
Flavoured Base q.s
Approved colour used

1.2 Pharmaceutical form
Liquid Orals- Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 15 ml contains:
Lactulose Concentrate USP equivalent to Lactulose 10 gm
Flavoured Base q.s
Approved colour used

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:
Liquid Orals- Solution
Yellow coloured, clear syrupy liquid having saunf flavour

4. CLINICAL PARTICULARS:
4.1 Therapeutic indications:
For the relief of occasional constipation and of chronic portal hypertension and hepatic encephalopathy.
Recommended route of administration: Oral

4.2 Posology and method of administration
Solution for oral route of administration
Dosage: As directed by the physician
In constipation
15 to 45 ml per day, depending on the severity of the condition
In Hepatic Encephalopathy:
30 to 50 ml three times daily or as directed by the physician.

4.3 Method of administration:
Oral

Direction for use:
SHAKE WELL BEFORE USE. Replace cap tightly immediately after each use.

4.4 Contraindications:
- Patients on low galactose diet or lactulose intolerance.
- Patients with gastrointestinal obstruction.

4.5 Special warning and precautions for use
Lactulose should not be given to patients with galactosaemia or intestinal obstruction. It should not be used in patients on a low galactose diet and care should be taken in patients with lactose intolerance or in diabetic patients because of the presence of some free galactose & lactose.

4.7 Interaction with other medicinal products and other forms of Interactions
Due to the lowering the pH in the colon, drugs that have a colon pH dependent release (such as 5- ASA agents) may be inactivated.

4.10 Pregnancy and lactation
This medicine may be used as prescribed during pregnancy and lactation.

4.11 Effects on ability to drive and use machines
Not relevant.

4.12 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, belly ache and diarrhoea may occur. In such a 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.

4.13 Overdose and special antidotes
Prolonged use or excessive dosage may result in diarrhea with excessive loss of water and electrolytes, particularly potassium.

5. PHARMACOLOGICAL PROPERTIES :
5.1 Pharmacodynamics Properties
Pharmacotherapeutic group: Osmotically acting laxatives. ATC code: Lactulose- A06AD11

Lactulose is broken down by colonic bacteria mainly into lactic acid. This exerts a local osmotic effect in the colon resulting in increased faecal bulk and stimulation of peristalsis. It may take upto 48 hours before an effect is obtained. When large doses are given for hepatic encephalopathy the pH in the colon is reduced significantly and the absorption of ammonium ions and other toxic nitrogeneous compounds is decreased, leading to a fall in blood – ammonia concentration and an
improvement in mental function.

5.2 Pharmacokinetic Properties
Lactulose is scantily absorbed after oral administration. 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 40-75 ml; at higher dosages, a part may be excreted unchanged.

5.3 Preclinical safety data
The results of acute, sub-chronic and chronic toxicity studies in various species indicate that the compound has very low toxicity. The effects observed, appear to be more related to the effect of bulk in the gastrointestinal tract than to a more specific toxic activity. In reproduction and teratology experiments in rabbits, rats or mice no adverse effects were found.

6. PHARMACEUTICAL PARTICULARS :
6.1 List of Excipients:
Riboflavin
Sodium Hydroxide Pellets
Flavour Saunf M5525

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container:
100 ml solution is packed in amber coloured pet bottle in carton along with product insert

6.6 Special precautions for disposal and other handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES
Marketing Authorization Holder:
Name: Galaxy Pharmaceutical ltd
Address: P.O. Box: 39107-00623, Nairobi (Kenya)

Name and Address of Manufacturer:
Name: **Enicar Pharmaceuticals Pvt. Ltd.,**
Address: Plot No.J-214,215,216, MIDC Tarapur, Boisar,
Tal: Palghar Dist Thane,
Tarapur – 401506
Country: India

8. MARKETING AUTHORISATION NUMBER

--

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

---

10. DATE OF REVISION OF THE TEXT
