1.6.1.1 Name of the medicinal Product

LAXALINK

1.6.1.1.1 Strength

Lactulose Solution USP 6400 mg/5ml

1.6.1.1.2 Pharmaceutical Form

Oral Solution

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Lactulose Concentrate USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/Tablet)	Reason for Inclusion
ACTIVE INGREDIENTS				
1.	Lactulose Solution	USP	6400.00	Laxative
EXCIPIENTS				
2.	Caramel (Double Strength)	IHS	2.000	Colouring Agent
3.	Flavour Aniseed oil	HIS	10.00	Flavouring Agent
4.	Sodium Hydroxide	BP	0.400	Buffering agent
5.	Purified Water	BP	Q.S.	Solvent

1.6.1.3 Pharmaceutical Form

Oral Solution

A yellow Colour to light brown coloured clear solution filled in bottle.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Constipation, Hepatic encephalopathy, Chronic portal hypertension.

1.6.1.4.2 Posology and Method of Administration

Constipation:

Adults: Initially 15 ml twice daily.

Children: 1 to 5 years – 5 ml twice daily.

5 to 10 years – 10 ml twice daily

Dosage may vary depending on the condition. The above dosage serves as a guide.

Eventually the dose should be adjusted, usually reduced to meet the needs of the individual.

Hepatic encephalopathy: Initially 30ml to 50ml, 3 times daily; adjust dose to produce 2 or 3 soft stools daily.

Method of administration: Oral.

1.6.1.4.3 Contraindications

Patients with cramps, colic, nausea, vomiting, or any undiagnosed abdominal conditions.

Patients on galactose-free diets.

Undiagnosed rectal bleeding.

Congestive heart failure or hypertension.

Diabetes mellitus.

Hypersensitivity to the ingredient

1.6.1.4.4 Special Warnings and Special Precautions for Use

Lactulose should not be given to children up to 6 years of age unless prescribed by a physician. Since children are not able to describe their symptoms precisely, proper diagnosis should precede the use of a laxative. This will avoid the complication of an existing condition (e.g. appendicitis) or the appearance of more severe side effects.

Lactulose should not be given to patients with intestinal obstruction. and on a low-galactose diet. Care should also be taken in patients with lactose intolerance or in diabetics because of the presence of some free galactose and lactose. In the event that an unusual diarrheal condition occurs, contact your physician.

Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no known human data on long-term potential for carcinogenicity, mutagenicity, or impairment of fertility.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

Chronic use or overuse of lactulose may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract and may interfere with potassium-retaining effects of potassium-sparing diuretics.

Non-absorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH.

1.6.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy: Lactulose solution should be used with caution during the first trimester of pregnancy.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lactulose solution is administered to a nursing woman.

1.6.1.4.7 Effects on ability To Drive and use Machines

None.

1.6.1.4.8 Undesirable Effects

Less frequently occurring: Gastro-intestinal disorders, Bloating, Cramping, Nausea, Diarrhoea, Gas formation, increased thirst.

1.6.1.4.9 Overdose

Prolonged use or excessive dosage may result in diarrhoea with excessive loss of water and electrolytes particularly potassium. It may also result in hypernatraemia and exacerbation of hepatic encephalopathy. Treatment should be symptomatic and supportive.

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Lactulose produces an osmotic effect in the colon resulting from biodegradation by colonic, bacterial flora into lactic, formic and acetic acid. Lactulose reduces intestinal absorption of ammonia.

1.6.1.5.2 Pharmacokinetic Properties

Lactulose passes almost completely unabsorbed from the gastro-intestinal tract and essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria mainly into lactic acid and small amounts of acetic and formic acids. Urinary excretion of unchanged lactulose has been reported to be 3% or less.

1.6.1.5.3 Preclinical Safety Data

Not applicable

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Caramel (Double Strength)
Flavour Aniseed oil
Sodium Hydroxide
Purified Water

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

1.6.1.6.5 Nature and Contents of Container

150 ml solution filled in 170 ml amber PET bottle having 25 mm "LPL" logo Printed Aluminium P.P. Cap & 10 ml measuring cup. Such one labeled bottle is packed in a printed carton with Packing Insert.

1.6.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-02764-665000
Fax: +91-02764-281809
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 **Date of Revision of the Text**

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable