SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lactulose 3.3g/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of Lactulose Solution Ph. Eur. contains 3.3g of Lactulose.

Excipient(s) with known effect
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In constipation and hepatic encephalopathy.

4.2 Posology and method of administration

Posology

Dose: expressed in twice of the syrup containing 3.3g/5ml

In constipation:

Adults
Initially 15ml twice daily, gradually reducing according to patients needs.

Paediatric Population
Under 1 year: 2.5ml
1 to 5 years: 5.0ml
5 to 12 years: 10.0ml twice daily gradually reduced.

Elderly
No special recommendations in the elderly.

In Hepatic Encephalopathy:

30 to 50ml 3 times daily, subsequently adjusted to produce 2 to 3 soft stools daily.

Method of administration

For oral administration only. Lactulose may be taken with water or fruit juice.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the related substances listed in section 6.1.

Lactulose Solution should not be given to patients with gastro-intestinal obstruction.

Contains galactose: Patients with rare hereditary problems of galactose intolerance e.g. galacotosaemia, or glucose-galactose malabsorption should not take this medicine.

Contains lactose: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use

Lactulose Solution should be used with caution in patients who are diabetic.

The product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine (see section 4.3).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

There is no evidence to suggest that Lactulose cannot be used in pregnancy or in lactation.

4.7 Effects on ability to drive and use machines

Lactulose Solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Side effects occur rarely. Flatulence, cramps, abdominal discomfort have occurred seldomly especially when therapy is initiated. (These symptoms occur in about 20% of patients receiving full doses of the drug). Nausea and vomiting have also been reported particularly with higher dosage.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Excessive dosage can cause diarrhoea, loss of fluid and potassium and exacerbation of hepatic encephalopathy. Lost fluid and electrolytes must be replaced and dosage reduced.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lactulose is an osmotic laxative. Its laxative action is due to a non-specific response to the acidity of the bowel contents which occur when Lactulose is metabolised by saccharolytic enzymes of the colon flora into organic acid such as lactic acids.

5.2 Pharmacokinetic properties

Lactulose is not absorbed or metabolised in the small intestine and is only partially absorbed upon reaching the colon. It is metabolised in the colon by the action of the colon flora i.e. saccharolytic enzymes of the flora degrade Lactulose into organic acids such as lactic acid.

The amount of unmodified Lactulose in the urine is very slight and even more remote in the faeces or bile.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No added excipients. Lactulose solution may however, contain the following related substances:

Galactose	nmt 15.0% of the lactulose content
Lactose	nmt 10.0% of the lactulose content
Epilactose	nmt 10.0% of the lactulose content
Tagatose	nmt 4.0% of the lactulose content
Fructose	nmt 1.0% of the lactulose content

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep tightly closed. Store in a cool dry place below 25°C.

6.5 Nature and contents of container

White plastic containers and caps 1000ml, 500ml. 300ml and 200ml.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

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PL32515/0055

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