Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lactecon 3.335g/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lactulose 3.335g per 5 ml oral solution (as Lactulose, liquid 667 g/l).

For a full list of excipients, see section 6.1.

Lactecon contains residues from the route of production with known effect, see section 4.4

3 PHARMACEUTICAL FORM

Oral solution.

A clear, viscous liquid, colourless to brownish yellow.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

(1) In the symptomatic treatment of constipation.
(2) In the treatment of hepatic encephalopathy.

4.2 Posology and method of administration

The lactulose solution may be administered diluted or undiluted.

A single 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 sufficient amounts of fluids 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.

	Startingdose daily	**Maintenancedose daily**
Adults and adolescents (≥ 15 years)	15-45 ml	15-30ml
Children (7-14 years)	15 ml	10-15 ml

Children (1-6 years)	5-10 ml	5-10 ml
Infants under 1 year	2.5-5 ml	up to-5 ml

Dosing in hepatic encephalopathv:
Adults:
Starting dose: 3 to 4 times daily 30-45 ml.
This dose may be adjusted to the maintenance dose to achieve 2 to 3 soft stools per day.

Special populations:

Paediatric population
The safety and efficacy of Lactecon in children (newborn to 18 years of age) with hepatic encephalopathy have not been established. No data are available.

Elderly patients
No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Patients with renal or hepatic insufficiency
No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Method of administration
Oral use.
For Lactecon in bottles the measuring cup may be used to administer the appropriate dose.

4.3 Contraindications

- Use in patients with galactosaemia.
- Hypersensitivity to the active substance or lactose, galactose, fructose or sulphite (see section 4.4).
- Gastrointestinal obstruction, perforation or risk of perforation.

4.4 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 insufficient therapeutic effect after several days the dose and/or additional measures should be re-considered. Long term use of this product is inadvisable except under medical supervision.

The dose normally used in constipation should not pose a problem for diabetics.

The dose used in the treatment of hepatic encephalopathy is usually much higher and may need to be taken into consideration for diabetics.

As diarrhoea induced by lactulose may lead to electrolyte imbalance, use with caution in patients prone to developing electrolyte disorders (e.g. patients with renal or hepatic impairment, patients receiving concomitant diuretics).

It should be taken into account that the defaecation reflex could be disturbed during the treatment.

Information on residues from manufacturing with known effect:
This product contains lactose, galactose and fructose from the route of production. Therefore, patients with the rare hereditary problem of galactose or fructose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Lactulose should be administered with care to patients who are intolerant to lactose.

This product contains sulphite from the route of production.

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

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.

Lactecon can be used during pregnancy.

Lactation
No effects on the breastfed newborn/infant are anticipated, since the systemic exposure of the breast-feeding woman to lactulose is negligible.

Lactecon can be used during breast-feeding.

Fertility
No effects are to be expected, since systemic exposure to lactulose is negligible.

4.7 Effects on ability to drive and use machines

The product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
Flatulence may occur during the first few days of treatment. As a rule it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhea may occur. In such a case the dosage should be decreased (see section 4.9).

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 diarrhea.

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)].

MedDRA SOC	**Frequency category**		
	Very common	**Common**	**Uncommon**
Gastrointestinal disorders	Diarrhoea	Flatulence, abdominal pain, nausea, vomiting	
Investigations			Electrolyte imbalance due to diarrhoea

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

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 national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 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 diarrhoea or vomiting may require correction of electrolyte disturbances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives.

ATC code: A 06A D11.

In the colon, lactulose is broken down by colonic bacteria into low molecular weight 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 the colonic contents. These effects stimulate the peristalsis of the colon and return the consistency of the stools. The constipation is cleared and the physiological rhythm of the colon is reinstated.

In hepatic encephalopathy (HE), the effect has been attributed to the 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 the alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilise ammonia for bacterial protein synthesis. Within this context, however, it should be realised that hyperammonemia alone cannot explain the neuropsychiatric manifestations of HE. The ammonia however might serve as a model compound for other nitrogenous substances.

5.2 Pharmacokinetic properties

Lactulose is poorly absorbed after oral administration and 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 proportion 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 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

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

Bottles of HDPE with polypropylene closures, containing 200, 300, 500 or 1000 ml; with a polypropylene measuring cup. The graduations on the measuring cup are: 2.5 ml, 5 ml, 10 ml, 15 ml, 20 ml, 25 ml and 30 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Mylan IRE Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER

PA2010/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 28 July 2010

10 DATE OF REVISION OF THE TEXT

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