

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lactecon 3.335g/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lactulose oral solution contains 3.335g of lactulose per 5ml.

For a full list of excipients, see section 6.1.

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.

For Lactecon in bottles the measuring cup may be used.

Dosing in constipation

Lactulose may be given as a single daily dose or in two divided doses, using the measuring cup.

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.

	Starting dose daily	Maintenance dose daily
Adults and adolescents (≥15 years)	15-45 ml	15 - 30 ml
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 encephalopathy - for adults only:

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.

Paediatric population

The safety and efficacy in children (newborn to 18 years of age) with HE 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.

4.3 Contraindications

- Use in patients with galactosaemia.
- Hypersensitivity to any of the components of the product.
- Gastrointestinal obstruction, digestive perforation or risk of digestive 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.

Lactecon should be administered with care to patients who are intolerant to lactose. (see section 6.1).

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.

This product contains lactose, galactose and small amounts of fructose. Therefore, patients with the rare hereditary problem of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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 effectsSummary 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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$)].

MedDRA SOC	Frequency category			
	Very common	Common	Uncommon	Rare
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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@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

Lactecon does not contain any excipients, but may contain sugars (e.g. lactose, galactose, fructose) from the route of synthesis.

May contain sulfite from the route of synthesis.

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

Date of first authorisation: 08 December 2000

Date of last renewal: 28 July 2010

10 DATE OF REVISION OF THE TEXT

December 2018