1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

LACSON 3,3 g per 5 ml syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of LACSON contains 3,3 g lactulose.

Contains sugar: Lactulose 3,3 g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

A colourless to brownish-yellow, clear or not more than slightly opalescent solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

LACSON is indicated for the management of:

- **Constipation**

  Particularly when associated with laxative habituation or for those patients in whom constipation presents a special problem, e.g. children, obstetric and post-surgical patients.

- **Chronic portal hypertension and hepatic encephalopathy**

  Hepatic coma or precoma stages where hyperammonaemia is present.

4.2 Posology and method of administration

Posology

Constipation:

Dosage can vary widely with the severity of the condition. A relatively large initial dose should be followed by a smaller maintenance dose after the first three days of treatment. Only one dose daily needs to be taken, preferably after breakfast.

Adults:

Usual starting dose: 30 ml (6 x 5 ml medicine measures).

Maintenance dose: 15 ml to 30 ml (3 to 6 x 5 ml medicine measures).

Chronic portal hypertension and hepatic encephalopathy:

Adults

Initial dose: 30 ml to 50 ml (6 to 10 medicine measures) three times daily.

Maintenance dose:

30 ml to 45 ml (6 to 9 medicine measures) three or four times daily; this is adjusted such that there are two or three soft stools daily and a faecal pH of 5 to 5,5.

Maintenance of the proper faecal pH is essential for appropriate effects on intestinal elimination of ammonia.

Paediatric population

Constipation

Usual starting dose

Children (6 to 14 years): 15 ml (3 x 5 ml medicine measures).

Children (1 to 5 years): 10 ml (2 x 5 ml medicine measures).

Infants: 5 ml (1 x 5 ml medicine measure).

Maintenance dose:

Children (6 to 14 years): 10 ml to 15 ml (2 to 3 x 5 ml medicine measures).

Children (1 to 5 years): 5 ml to 10 ml (1 to 2 x 5 ml medicine measures).

Infants: 2,5 ml to 5 ml (½ to 1 x 5 ml medicine measures).

Chronic portal hypertension and hepatic encephalopathy:

The safety and efficacy of LACSON in children has not been established.

Method of administration

For oral use.

For constipation, only one dose daily needs to be taken, preferably after breakfast.

4.3 Contraindications

LACSON is contraindicated in:

- Patients with hypersensitivity to lactulose or to any of the excipients in LACSON (see section 6.1).
- Galactosaemia including patients on a galactose free diet.
- Patients with 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 (see section 4.3).

In case of insufficient therapeutic effect after several days the dose and/or additional measures should be re-considered (see section 4.2).

Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.
Diarrhoea also indicates overdosage.

Although occasionally nausea and meteorism or flatulence have been reported on the high initial dosages used, these effects normally disappear when the maintenance dosage has been reached (see section 4.8).

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

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 lactulose is not absorbed to any significant degree, it may be given to diabetics.
However, care should be taken in patients with lactose intolerance or in diabetic patients because of the presence of some free galactose and lactose.

Paediatric population

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

LACSON contains sugars such as fructose, galactose and lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, total lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take LACSON.

4.5 Interaction with other medicines and other forms of interaction

For management of chronic portal hypertension and encephalopathy other laxatives should not be employed concurrently in order to avoid inadequate acidification of the stool.

4.6 Fertility, pregnancy and lactation

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to lactulose, as contained in LACSON, is negligible.

LACSON can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to lactulose, as contained in LACSON, is negligible.

LACSON can be used during breastfeeding.

Fertility

No effects are to be expected, since systemic exposure to lactulose, as contained in LACSON, is negligible.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Gastrointestinal disorders	Diarrhoea, flatulence, abdominal pain, nausea, vomiting		Abdominal discomfort, cramps, meteorism
Investigations		Electrolyte imbalance due to diarrhoea	

b) Description of selected adverse reactions

Nausea and vomiting have been reported following high doses. Prolonged use or overdosage may result in diarrhoea with excessive loss of water and electrolytes, particularly potassium.

c) 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9 Overdose

Symptoms

If the dose is too high, the following may occur: diarrhoea, loss of electrolytes and abdominal pain (see sections 4.4 and 4.8).

Treatment

Cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

No specific antidote. Symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 11.5 Laxatives.

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD11

Mechanism of action

Lactulose is a synthetic disaccharide derivative of lactose, and acts by its osmotic properties in the luminal fluid. The primary osmotic effect of lactulose, which is not absorbed in the upper intestine, may be augmented in the distal ileum and colon by bacterial metabolism of the disaccharide to lactate and other organic acids that are only partially absorbed. There is speculation that the concomitant reduction in luminal pH enhances motility and secretion.

The increased osmotic activity in the lumen that follows administration of lactulose results in modest accumulation of fluid and passage of soft, formed faeces in 1 to 3 days. Another important aspect of the action of lactulose is reduction of intestinal absorption of ammonia, presumably because of reduced production and increased utilisation of ammonia by intestinal bacteria and enhanced excretion of ammonia in the faeces.

5.2 Pharmacokinetic properties

Lactulose is poorly absorbed after oral administration and it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25 g to 50 g or 40 ml to 75 ml; at higher dosages, a proportion may be excreted unchanged.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep in original packaging until required for use.

6.5 Nature and contents of container

150 ml or 500 ml is packed into an amber, round, polyvinylchloride bottle and sealed with a white polypropylene screw cap.

150 ml or 500 ml is packed into an amber, round, PET bottle and sealed with a white polypropylene screw cap.

Not all packs and pack sizes are necessarily marketed.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8 REGISTRATION NUMBER

Z/11.5/0055

9 DATE OF FIRST AUTHORISATION

Date of registration: 01 April 1992

10 DATE OF REVISION OF TEXT

21 June 2021

Namibia: NS0 04/11.5/0029

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