Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Laxiwal Solution

2. Qualitative and quantitative composition
Each 15ml contains: Lactulose ……10gm

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Colourless to amber coloured clear solution with lemon flavour.

4. Clinical particulars

4.1 Therapeutic indications
For symptomatic relief of constipation not directly due to any organic obstructive lesion of bowel. It is recommended portal systemic encephalopathy and in salmonellosis, as well. Lactulose is a type of sugar that is broken down into mild acids in the colon. These acids draw water into colon and thereby help soften the stool.

4.2 Posology and method of administration
Posology
The lactulose solution may be administered diluted or undiluted. Each dose may if necessary be taken with water or fruit juices, etc. Each 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 (1.5–2 litres, equal to 6-8 glasses) during the day. For lactulose in bottles the measuring cup may be used. For lactulose in 15 ml single dose sachets the corner of the sachet should be torn off and contents taken immediately.

Method of administration
For administration by the oral route

4.3 Contraindications
Patient with diabetics and those requiring a diet low in galactose and undergoing a proctoscopy or colonoscopy. Avoid lactulose, or dose reduction /monitoring necessary in any of the conditions.

4.4 Special warnings and precautions for use
Keep out of the reach of children, prolonged uses is best avoided

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may decrease the effects of lactulose. Talk to your doctor and pharmacist before taking any prescription or ever the counter medicines for heartburn or any other aliment.

4.6 Pregnancy and Lactation

Lactulose is in FDA pregnancy category B. this means that it is not likely to harm an unborn baby. However. consult your physician before taking Laxiwal , if you are pregnant. It is not known whether Lactulose passes into breast milk. Consult your doctor before using it, if you are nursing a newborn.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Flatulence may occur during the first few days of treatment. As a rule it disappears after a couple of days. When dosages higher than instructed are used, abdominal pain and diarrhea may occur. In such a case the dosage should be decreased. See also overdose section 4.9.

If high doses (normally only associated with portosystemic encephalopathy, PSE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhea. Dosage should then be adjusted to obtain two or three formed stools per day.

Because the following reactions were reported spontaneously from a population of uncertain size it is not possible to reliably estimate their frequency.

Gastrointestinal disorders

Common effects include: flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhea. Investigations Electrolyte imbalance due to diarrhea.

Investigations

Electrolyte imbalance due to diarrhea.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

If the dose is too high, the following may occur:

Symptom: diarrhea and abdominal pain.

Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances. No specific antidote. Symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives
ATC code: A 06A D11

Mechanism of action
In the colon lactulose is broken down by colonic bacteria into low molecular 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 colonic contents. These effects stimulate peristalsis of the colon and return the consistency of the stool. The constipation is cleared and the physiological rhythm of the colon is reinstated.
In hepatic encephalopathy (HE) the effect has been attributed to 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 alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.

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 25-50 g or 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 the 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

Sodium Methylparaben BP
Sodium Propylparaben BP
Citric Acid Monohydrate BP
Lemon No. 1 (Quest) IH
Purified Water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

24 months
Use within 12 months of first opening

6.4 Special Precautions for storage

Store at temperature below 30oC. Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolong exposure to freezing temperature may cause change to a semisolid too viscous to pour. Viscosity will return to normal upon warming to room temperature.
Protect from light.

6.5 Nature and Content of container

PET Bottle of 100 ml and 200 ml packed in a Carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Wallace Pharmaceuticals Pvt. Ltd.
3 rd Floor, Dempo Trade Centre Building
Patto Plaza, EDC Complex, Panaji, Goa – 403 001
Tel: 91-832-2438156 to 61
Fax 91-832-2438151

8. Marketing Authorization Number

CTD11399

9. Date of first authorization/renewal of the authorization

09/08/2024

10. Date of revision of the text

18/05/2025