SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lactulose Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 3.35 g of lactulose.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Lactulose solution is indicated for the treatment of constipation and hepatic encephalopathy (portal systemic encephalopathy) including hepatic coma.

4.2. Posology and method of administration

For oral administration.

Constipation.

Initially :	Adults:	15 ml twice daily
	Children 5 - 10 years:	10 ml twice daily
	Children 1-5 years:	5 ml twice daily
	Babies (under 1 year):	2.5 ml twice daily

The dosage should then be adjusted to the needs of the individual. Each dose may if necessary be taken with water or fruit juices, etc.

Hepatic Encephalopathy.

Adults (including the elderly): Initially 30 - 50 ml (6-10 x 5 ml spoonfuls) three times daily according to individual requirements. The dose should be adjusted subsequently to produce two or three soft stools each day.

Children: no dosage recommendations for this indication.

4.3. Contraindications

Lactulose is contra-indicated in patients with gastrointestinal obstruction and in patients with galactosaemia or lactose intolerance.

4.4. Special warnings and precautions for use

Use with caution in diabetic patients. The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of (pre)coma hepaticum is usually much higher and may need to be taken into consideration for diabetics.

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

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

In case of insufficient therapeutic effect after several days, consultation of a physician is advised.

4.5. Interactions with other medicinal products and other forms of interaction

None known.

4.6. Pregnancy and lactation

Limited data on pregnant patients indicate neither malformative nor foeto/neonatal toxicity.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).

The use of lactulose may be considered during pregnancy if necessary. Lactulose should be used with caution during the first trimester of pregnancy.

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

Lactulose can be used during breast-feeding.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Side-effects rarely occur after administration of lactulose solution. Mild transient effects such as cramps and abdominal distension which subside after the initial stage of treatment have been reported.
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 diarrhoea 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 diarrhoea. Dosage should then be adjusted to obtain two or three formed stools per day.

Gastrointestinal disorders
Flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhoea.
High doses may provoke nausea which can be minimised by administration with water, fruit juice or with meals.

Investigations
Electrolyte imbalance due to diarrhoea.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

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

Symptom: diarrhoea and abdominal pain.

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

ATC Code: AO6A D11 Osmotically acting laxatives.

Lactulose solution is a laxative preparation providing a natural substrate for the saccharolytic bacterial flora in the colon.

The active ingredient, lactulose is not hydrolysed in the small intestine and is transported to the colon and is metabolised in the colon by the sacchrolytic bacteria, producing low molecular weight organic acids, mainly lactic acid, which lower the pH of the colon contents, promote the retention of water by an osmotic effect, and more water is drawn into the bowel thus increasing peristaltic activity.

In hepatic encephalopathy the effectiveness of lactulose solution may be associated with the decrease in the relative concentration of free ammonia.

5.2. Pharmacokinetic properties

Lactulose is minimally absorbed; therefore, the kinetics of the absorbed material are not relevant to the principal therapeutic action. Lactulose passes into the large bowel chemically unchanged. The breakdown products here are simple organic compounds like lactic and acetic acid.

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

Lactose
Galactose.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

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

6.5. Nature and contents of container

White polyethylene bottle with either HDPE screw cap (polypropylene inner) or HDPE screw cap with a polypropylene inner and expanded polyethylene (EPE) wad liner or polypropylene lid with an EPE wad liner and a polyethylene tamper evident band or a polypropylene flip top cap with a LP-E (lift ‘n’ peel (heat induction seal)).

The bottles contain 100, 150, 200, 300, 500, 1000, 2500 or 5000 ml of solution.

Not all pack sizes may be marketed.

6.6. Instruction for use and handling (and disposal)

Not applicable.

7. MARKETING AUTHORISATION HOLDER

TEVA UK Limited,
Brampton Road, Hampden Park,
Eastbourne, East Sussex, BN22 9AG

8. MARKETING AUTHORISATION NUMBER

PL 00289/0285

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 May 1999

10. DATE OF REVISION OF THE TEXT

29/08/2018

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