SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DUOLAC

(Lactitol Monohydrate Solution)

Strength

Composition:

Each 15 ml contains:

Lactitol Monohydrate USP 10gm

Flavoured aqueous base q.s

Approved colour used.

Pharmaceutical form

Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lactitol Monohydrate Solution-10gm

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DUOLAC Solution is indicated for the treatment of constipation and the prevention of hepatic encephalopathy.

4.2 Posology and method of administration

Posology

Constipation

DUOLAC Solution should be administered once daily, in the morning or evening, at mealtimes. In some cases, the laxative action may not begin until the second or third day after the initial dose. Patients should maintain an adequate daily fluid intake.

Posology:

Adults: The usual recommended dose of DUOLAC Solution is 15 to 30 ml per day.

Paediatric: The usual recommended dose of DUOLAC Solution for children in the age group of 2 to 6 years is 10 ml per day.

For children above the age of 6 years, the recommended dose is 10 to 15 ml per day.

The recommended dose for infants or breastfeed babies is 5 ml per day.

Hepatic Encephalopathy

Adults: For the prevention of hepatic encephalopathy, the recommended dose of DUOLAC Solution is 30 ml once daily in the evening.

The usual recommended dose for the treatment of the acute phase of hepatic encephalopathy is 45 to 90 ml in three divided doses along with main meals.

Paediatric: The mean dosage is 0.25 g/kg body weight daily.

Aged 1 to 6 years: 2.5 to 5 g per day

Aged 6 to 12 years: 5to 10 g per day

Aged 12 to 16 years: 10 to 20 g per day

For taking fraction doses (e.g. 2.5 or 5 g) of presented 10 g of lactitol, the whole 10 g should be dissolved in water. Half of the solution (5g) and one-fourth (2.5 g), respectively, should be taken. The rest of the solution should be discarded.

The effect of lactitol has been found mostly to occur within a few hours after intake. But, in some cases, the first laxative response may be delayed until the second or third day of administration. Therefore, patients should be advised to maintain an adequate daily fluid intake.

Portal Systemic Encephalopathy

The dose should be adjusted according to the severity of the patient's disease and his or her individual response.

The initial recommended dose is 0.5 to 0.7 g/kg body weight daily, divided into three daily doses with meals and subsequently adjusted to produce two soft stools daily OR As directed by the physician.

Method of administration: Oral

4.3 Contraindications

DUOLAC is contraindicated in:

Appendicitis

Patients with intestinal obstruction, where an underlying organic lesion of the gastrointestinal tract is suspected, or in cases of unexplained abdominal pain or bleeding.

Hypersensitivity to the drug or any other component of the formulation.

Galactosaemia.

4.4 Special warnings and precautions for use

Absorption of lactate from the colonic metabolism of lactitol can potentially result in

acid-base disturbances, and diarrhoea induced by lactitol can be associated with hypokalaemia and hypernatraemia. Potassium deficiency may increase the risk of the toxic effects of glycosides in patients receiving concomitant therapy.
Periodic monitoring of serum electrolytes, blood glucose and blood lactate is suggested. If watery stools are noticed, one should either reduce the quantity of administration. As with all laxatives, any pre-existing electrolyte or water balance abnormalities must be corrected. Blood electrolyte levels should be monitored regularly in elderly or debilitated patients on long-term treatment.
Patients who complain of nausea should be advised to take lactitol with meals.
Lactitol is not recommended in case of ileostomy or colostomy. Facial impaction should be treated by alternative methods prior to using lactitol.
Following treatment with lactitol, hydrogen may accumulate in the bowel. Patients who need to undergo electro cauterization procedures should, therefore, have a thorough bowel cleansing with a non-fermenetable solution.

4.5 Interaction with other medicinal products and other forms of interaction

Lactitol can increase the potassium losses caused by other medicines (e.g. thiazide diuretics, corticosteroids, carbenoxolone, amphotericin B)
Potassium deficiency may increase the risk of the toxic effects of glycosides in patients receiving concomitant therapy.
Lactitol can increase digitalis toxicity. Concomitant administration of lactitol with neomycin can cause an increase in neomycins activity.
If broad-spectrum antibacterial agents and antacids are administered along with lactitol, it can cause a reduction in the acidification effect of lactitol on the intestinal microflora and consequently limit therapeutic efficacy.

4.6 Fertility, pregnancy, and lactation

Pregnancy
This drug should be prescribed only if the potential benefits outweigh the potential risks to the foetus.

Lactation
There have been no studies on the excretion of lactitol into breast milk.It is unlikely that the use of lactitol during breast feeding would have any clinical effect on the child, because its absorption is minimal. But, this drug should be prescribed only if the potential benefits of the drug outweigh the risks.

4.7 Effects on ability to drive and use machines
None.

4.8 Undesirable effects
Abdominal distension, cramps and flatulence have occurred most frequently (30% to 100% of patients): these effects are most prevalent during the first 10 days of treatment and tend to subside after continued administration. Other less frequent side effects include abdominal discomfort, nausea, dyspepsia, epigastric pain, urgency, or anal pruritus and vomiting in rare cases. Generally,diarrhoea occurs with excessive doses of lactitol; but, some patients may experience diarrhoea at the recommended dosage. A reduction in dosage will overcome this.

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 Pharmacovigilance
Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

The appearance of diarrhoea and abdominal cramps is a sign of overdosage and dose reduction may be required.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Lactitol is a synthetic, lactulose-like disaccharide. It is derived from lactose and is minimally absorbed following oral administration. It is more palatable, better tolerated and produces a more predictable cathartic activity than lactulose. Lactitol has calorific value of 2 kcal/g (8.5 KJ/g) and has no effect on blood glucose levels. It can, therefore, be given to diabetes patients.

Mechanism of Action

Lactitol is a disaccharide derivative consisting of galactose and sorbitol, which is only minimally absorbed and is not hydrolysed by the disaccharidases of the gastrointestinal tract and, thus, reaches the colon unchanged.In the colon, it is broken down into short chain, organic acids, mainly acetic, propionic and butyric

acid, by the intestinal flora, in particular by the bacteroides and lactobacilli, thus acidifying the contents of the colon. The effect of this acidification reduces the absorption of ammonia. The transformation of lactitol into low- molecular weight organic acid results in an increase in osmotic pressure in the colon, thereby causing an increase in the stool water content and stool volume, which explains the laxative affect.

The mechanism of action of lactitol in hepatic encephalopathy is most likely related to suppression of the absorption of unionized ammonia via lowering of colonic pH; a cathartic action also enhances faecal nitrogen excretion and decreases intestinal transit time, with a reduction in the time for production and absorption and other potential toxins.

5.2 Pharmacokinetic properties

Lactitol is not significantly absorbed in the small intestine; only 0.5% to 2% of a dose is partially absorbed as unchanged lactitol. While 64% of the dose is absorbed by the colonic mucosa as volatile fatty acids, 6.5% is excreted in the faeces. Small amounts of unchanged lactitol appear in the urine (2% or less of a dose).

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Paraben BP, Sodium Propyl Paraben BP, Sorbitol 70% solution BP, Propylene Glycol BP, Benzoic Acid BP, Citric Acid Monohydrate BP, Colour Ponceau 4R IH, Colour Sunset Yellow FCF Supra IH, Flavour Mango Alphanso M-8929 IH, Purified Water BP.

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C in a cool dry place.

Protect from light.

Keep medicine out of reach of children.

6.5 Nature and contents of the container

200 ml Amber coloured PET bottle packed in a carton with a leaflet and measuring cup. 50 such cartons are wrapped with PVC Shrink and are packed in 5-Ply Corrugated Box and sealed with Transparent BOPP Tape.

6.6 Special precautions for disposal <and other handling>

No special requirements

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

MANUFACTURER

ENICAR PHARMACEUTICALS PVT. LTD

J-214, 215,216, M.I.D.C., Tarapur, Boisar, Dist Palghar 401 506.

Ph. - +91-2525-279918 / 19 Fax - +91-2525-273523

MARKETING AUTHORIZATION HOLDER

GALAXY PHARMACEUTICAL LTD
1ST FLOOR, DOCTORS PARK, 3RD PARKLANDS AVENUE PO BOX 39107-00623, NAIROBI, KENYA

8. MARKETING AUTHORIZATION NUMBER

H2017/CTD2824/019

9. Date of first Authorization /renewal of the authorization:

June 2026

10. Date of revision of text