Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
ECOLAC Solution

2. Qualitative and quantitative composition
Each 5ml contains Lactulose 3.4 gm (as lactulose concentrate USP)
For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Solution

Clear pale-yellow solution.

4. Clinical particulars

4.1 Therapeutic indications
Lactulose solution is used in the treatment of constipation and hepatic encephalopathy (portal systemic encephalopathy); hepatic coma.

4.2 Posology and method of administration
Portal-Systemic Encephalopathy
The usual dosage is 30 to 50ml three or four times daily. The dosage may be adjusted every day or two to produce two or three soft stools daily. Hourly doses of 30 to 50 ml of Lactulose solution may be used to induce the rapid laxation indicated in the initial phase of the therapy of Portal systemic encephalopathy (PSE). When the laxative effect has been achieved, the dose of Lactulose may then be reduced to the recommended daily dose. Improvement in the patient's condition may take 24 to 48 hours to occur. Continuous long-term therapy is indicated to lessen the severity and prevent the recurrence of PSE. The dose of Lactulose for this purpose is the same as the recommended daily dose. In the treatment of acute episodes of PSE, a rapid response is desirable. In such cases it is important to avoid under dosage, and 50 ml every 1 to 2 hours can be given if necessary until two loose bowel actions have occurred. Thereafter, doses may be reduced to usual doses (30 ml four times daily). The administration of lactulose by retention enema is an alternative technique. This can be prepared by diluting Lactulose solution, and is of considerable value especially in the unconscious patient. In such cases 300 ml of Lactulose solution may be mixed with 700 ml of water or normal saline to be used as a retention enema; the enema is to be retained for 30 to 60minutes, and repeated every 4 to 6 hours until the patient is able to take oral medication.

Chronic constipation
Dosage is individualised and depends somewhat on the severity of the constipation. Adults - The usual initial dose is 15 to 30 ml daily as a single dose or in two divided doses. The dose may be increased to 45 ml daily if necessary. Since Lactulose solution relieves constipation by producing a physiological change in the colon, it may take from 24 to

48hours before normal defaecation occurs. After three days, the dose may be reduced to 10 to 25 ml daily for maintenance. More serious constipation and/or constipation such as that caused by chemotherapy agents may require higher dosages.

Children
It is recommended that if Lactulose solution is given to infants and children, this should be done under medical supervision. The usual initial daily doses (for the first three days) are as follows:
7 to 14 years: 15 ml

4.3 Contraindications

Lactulose solution should not be given to:
Patients who require a low lactose diet Patients with galactosaemia or disaccharide deficiency Patients on a galactose and/or lactose free diet Patients with intestinal obstruction.

4.4 Special warnings and precautions for use

A theoretical hazard may exist for patients being treated with lactulose who may be required to undergo electro cautery procedures during proctoscopy or colonoscopy. Accumulation of H gas in significant concentration in the presence of an electrical spark may result in an explosive reaction. Although this complication has not been reported with lactulose, patients on lactulose therapy undergoing such procedures should have a thorough bowel cleansing with a non-fermentable solution. Insufflation of CO as an additional safeguard may be pursued 2but is considered to be a redundant measure. Lactulose Solution contains galactose and lactose (less than 0.3g/10 g as a total sum), it should be used with caution in diabetics. In the event that an unusual diarrheal condition occurs, contact your physician. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of neomycin and lactulose solution, although in some situations, the two drugs administered together are more effective than either one alone. Theoretically, the elimination of certain colonic bacteria by neomycin and possibly other anti-infective agents may interfere with the desired degradation of lactulose and thus prevent the acidification of colonic contents. There have been some reports that lactulose fermenting bacteria are relatively resistant to neomycin, which might explain why a combination could work in some cases. Thus, the status of the lactulose treated patient should be closely monitored in the event of concomitant oral antibiotic therapy. Other laxatives should not be used, especially during the initial phase of therapy for PSE because the loose stools resulting from their use may falsely suggest that adequate dosage has been achieved. Results of limited studies in rats and humans

suggest that non absorbable antacids administered concomitantly with lactulose may inhibit the desired decrease in faecal pH in the colon. The potential lack of desired effect of lactulose should be considered before a non-absorbable antacid is administered concomitantly with lactulose.

4.6 Pregnancy and Lactation

Use in Children

It is recommended that if lactulose syrup is given to infants or children for periods greater than one month that this should be done under medical supervision.

Pregnancy

Reports on the clinical experience of lactulose and data from animal reproduction studies have not revealed any increase in embryotoxic hazard to the foetus if used in the recommended dose during pregnancy. If drug therapy is needed in pregnancy the use of this drug is acceptable. Reproduction studies with daily oral doses of lactulose syrup up to 12ml/kg in mice and rats and 6mL/kg in rabbits have not revealed any evidence of an increased occurrence of foetal damage or other deleterious effects. Lactulose syrup has been shown to be safe and effective for the treatment of constipation associated with pregnancy when administered to women at different stages of pregnancy. Its use during pregnancy should be on the advice of a medical practitioner.

Breast-feeding

There is no data on the secretion of lactulose in breast milk or the effect on the breastfed infant. It should not be given to breastfeeding women unless the benefits to the mother outweigh the potential risks to the feeding infant.

Fertility

No known effect.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Precise frequency data are not available. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia, and hypernatremia. Nausea and vomiting have been reported.

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

There have been no reports of accidental overdosage. In the event of overdosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated. Complications of diarrhoea may include fluid loss, and electrolyte disturbances, such as hypokalaemia and hypernatremia, in which case treatment would consist of fluid and electrolyte replacement. Dialysis data are not available for lactulose. Its molecular similarity to sucrose, however, would suggest that it should be dialyzable

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD11

Mechanism of action

Lactulose is poorly absorbed from the gastrointestinal tract and no enzyme capable of hydrolysis of this disaccharide is present in human gastrointestinal tissue. As a result, oral doses of lactulose reach the colon virtually unchanged. In the colon, Lactulose is broken down primarily to lactic acid, and also to small amounts of formic and acetic acids, by the action of colonic bacteria, which results in an increase in osmotic pressure and slight acidification of the colonic contents. This in turn causes an increase in stool water content and softens the stool. Since Lactulose does not exert its effect until it reaches the colon, and since transit time through the colon may be slow, 24 to 48 hours may be required to produce desired bowel movement. When larger doses are given for hepatic encephalopathy the pH in the colon is reduced significantly by this acid production and the absorption of ammonium ions and other toxic nitrogenous compounds is decreased leading to a fall in blood-ammonia concentration. Lactulose given orally to man and experimental animals resulted in only small amounts reaching the blood. Urinary excretion has been determined to be 3% or less and is essentially complete within 24 hours.

5.2 Pharmacokinetic properties

Experimental data on lactulose given orally to humans indicate that lactulose is poorly absorbed from the gastrointestinal tract and no enzymes capable of hydrolysis of lactulose into its component monosaccharides are known to be present in human gastrointestinal tissue. Lactulose reaches the colon virtually unchanged. There it is metabolised by colonic bacteria to low molecular weight acids, ie. Lactic acid and other short chain carboxylic acids. Lactulose given orally to humans results in only small amounts reaching the blood by absorption through the small intestine probably by a non-mediated diffusion mechanism. Otherwise, small increases in blood sugar levels are probably attributable to the small amounts of galactose and lactose also present in lactulose solution. Urinary excretion has been determined to

be3% or less and is essentially complete within 24 hours. A small quantity of lactulose is probably hydrolysed in the colon into its constituent monosaccharides, galactose and fructose. The end

5.3 Preclinical safety data
Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients
Not Applicable

6.2 Incompatibilities
Not Applicable

6.3 Shelf-Life
30 months

6.4 Special Precautions for storage
Store below 30°C. Protect from light and moisture.

6.5 Nature and Content of container
100 ml solution filled in Amber coloured glass bottle

6.6 Special precautions for disposal and other handling
Not Applicable

7. Marketing Authorization Holder
Sterling Lab
57, Sipcot Industrial Complex
Hosur-635126 Tamilnadu, India

8. Marketing Authorization Number
H2021/CTD8240/16950

9. Date of first authorization/renewal of the authorization
01 September 2021

10. Date of revision of the text
20/08/2026