



AURA LIFECARE PVT. LTD.
Product: Lactulose Solution USP
MODULE: 1

Patient Information Leaflet

1. Name of the Product

Lactulose Solution USP

2. Description of the Product

Pale yellow colored, clear syrup

3. What is in the medicine?

Lactulose

4. Strength of the medicine

Each 15ml contains

Lactulose Concentrate USP

Eq. to Lactulose 10 gm

Flavored Syrupy Base

Color: Riboflavin

5. What is this medicine used for?

- Symptomatic treatment of constipation
- Treatment of portal systemic encephalopathy

6. How much and how often should you use this medicine?

The posology should be adjusted according to the individual needs of the patient. The starting dose can be adjusted after adequate treatment effect individually (maintenance dose). Several days (2-3 days) of treatment may be needed in some patients before adequate treatment effect occurs. In case of single daily dose, this should be taken at the same time of the day, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5- 2 l/day, equal to 6-8 glasses).

Constipation:

	Starting dose	Maintenance dose
--	---------------	------------------



AURA LIFECARE PVT. LTD.
Product: Lactulose Solution USP
MODULE: 1

Adults	15-45 ml	corresponding to 10-30 g lactulose	15-30 ml	corresponding to 10-20 g lactulose
--------	----------	------------------------------------	----------	------------------------------------

Paediatric population

	Starting dose		Maintenance dose	
Adolescents over 14 years	15-45 ml	corresponding to 10-30 g lactulose	15-30 ml	corresponding to 10-20 g lactulose
Children (7-14 years)	15 ml	corresponding to 10 g lactulose	10-15 ml	corresponding to 7-10 g lactulose
Children (1-6 years)	5-10 ml	corresponding to 3-7 g lactulose		
Babies	up to 5 ml	corresponding to up to 3 g lactulose		

If diarrhoea occurs, the dosing regimen should be reduced.

Treatment of portal systemic encephalopathy - for adults only:

Beginning with 30 - 50 ml 3 times daily (corresponding to 60 - 100 g Lactulose). The dosage has to be adopted to get 2-3 soft stools daily, pH of the stools should be between 5.0 to 5.5.

Method of administration

The lactulose solution may be administered diluted or undiluted. The dose should be titrated according to the clinical response. Lactulose may be given as a single daily dose or up to three divided daily doses, using the measuring cup.

A single dose of lactulose should be swallowed in one and should not be kept in the mouth for an extended period of time.

The duration of treatment has to be adopted according to the symptoms.

7. When should you not take this medicine?

Hypersensitivity to the active substance or to any of the excipients

Use in patients with galactosaemia.



AURA LIFECARE PVT. LTD.
Product: Lactulose Solution USP
MODULE: 1

Acute inflammatory bowel disease (ulcerative colitis, Crohn's disease), gastrointestinal obstruction or subocclusive syndromes, digestive perforation or risk of digestive perforation, painful abdominal syndromes of undetermined cause.

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 diarrhoea may occur. In such a case the dosage should be decreased.

Gastrointestinal disorders

Very common ($\geq 1/10$): flatulence, abdominal pain.

Common ($\geq 1/100 < 1/10$): nausea and vomiting; if dosed too high, diarrhoea.

Investigations

Electrolyte imbalance due to diarrhoea.

9. What other medicine or food should be avoided whilst taking this medicine

Contraindications of concomitant use

Lactulose may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.

With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.

10. What should you do if you miss a dose?

Try to make sure that you do not miss any doses. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

11. How should you keep this medicine?

No special requirements.



AURA LIFECARE PVT. LTD.
Product: Lactulose Solution USP
MODULE: 1

12. Signs and Symptoms of Overdosage

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.

13. What to do when you have taken more than the recommended dosage

If you have accidentally taken too many tablets, talk to your doctor straight away, or go to your nearest emergency unit. You may require medical attention. Remember to take your medicine with you, and show it to your doctor or the staff of the emergency unit.

14. Name/Logo of Manufacturer/Importer/Marketing Authorisation Holder

Sun Enterprises LTD

BP 1952

Kigali, Rwanda

15. Care that should be taken while taking this medicine

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

From the route of synthesis Lactulose may contain traces of sugars (not more than 67 mg/ml lactose, 100 mg/ml galactose, 67 mg/ml epilactose, 27 mg/ml tagatose and 7 mg/ml fructose).

Lactulose should be administered with care to patients who are intolerant to lactose.

The dose normally used in constipation should not pose a problem for diabetics. However, higher doses used for treatment of portal systemic encephalopathy may need to be taken into considerations for diabetics. 15 ml of Lactulose contain 42,7 KJ (10,2 kcal) = 0,21 bu.

The defecation reflex may be altered during the treatment with lactulose.

Patients with rare hereditary problems of galactose or fructose intolerance, lactase deficiency or glucose-galactose mal-absorption should not take this medicine.

For patients with gastro-cardiac syndrome (Roemheld syndrome) lactulose should only be taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after lactulose intake, the dose should be reduced or the treatment should be discontinued.



AURA LIFECARE PVT. LTD.
Product: Lactulose Solution USP
MODULE: 1

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

For elderly patients or patients that are in bad general condition and who take lactulose for more than a 6 months period, periodic control of electrolytes is indicated.

In patients with portal systemic encephalopathy, concomitant administration of other laxatives should be avoided, because it hinders the individualization of drug dose. Furthermore, for the patients referred above, it should be taken into account the chance of causing electrolyte imbalance and, mainly, hypokalaemia that could aggravate encephalopathy.

During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5-2 l/day, equal to 6-8 glasses).

Paediatric population

Use of laxatives in children should be exceptional and under medical supervision. Lactulose should be administrated with caution in infants and small children with autosomal recessive hereditary fructose intolerance.

16. Date of Revision of PIL
