Niprolac

Lactulose 3.35 gm/5ml
Oral Solution

Niprolac (Lactulose) is a synthetic disaccharide. Lactulose is metabolized in the colon by the saccharolytic bacteria, producing low molecular weight organic acids (mainly lactic acid), which lowers the pH of the colon contents, promote the retention of water by an osmotic effect; thus increasing peristaltic activity. Lactulose is minimally absorbed; therefore, the pharmacokinetics of the absorbed material are not relevant to the principal therapeutic action.

COMPOSITION

Each 5 ml oral solution contains Lactulose USP 3.35 gm.

INDICATION

1. Constipation (Chronic Constipation): In every case of chronic constipation, initial treatment should consist of a diet rich in fiber (vegetables, salads, fruits etc.) a generous amount of liquids and much physical exercise. **Niprolac** is only to be taken when these measures prove insufficient.
2. Intestinal flora disturbances: In

-damaged to intestinal flora (e.g. following long-term antibiotic treatment)

-gall bladder diseases

-intestinal diseases (Colitis, Diverticulosis, Megacolon)

3. Increased blood ammonia levels (hyper ammoniemia in hepatopathy, portal-systemic encephalopathy)

DOSAGE AND ADMINISTRATION

Dosage should be followed accurately unless otherwise specified.
1. In constipation (chronic constipation):

	Initially	In long-term therapy
Adults	3-6 tea-spoons daily	1½-6 tea-spoons daily
Children up to 14 years	3 tea-spoons daily	1-2 tea-spoons daily
Infants and toddlers	1-2 tea-spoons daily	1 tea-spoon daily

2. In damaged intestinal flora:
Adults: 1-2 tea-spoons daily
Children: 1 tea-spoon daily
3. For reduction of blood ammonia level:
Hyper-ammoniemia in hepatopathy- a maximum of 18-30 tea-spoons daily.
In portal systemic encephalopathy- hourly doses of 6-9 tea-spoons of Lactulose solution may be used to induce the rapid laxation. When the laxative effect has been achieved, the dose may then be reduced.

SIDE EFFECT

Occasionally flatulence, cramp and abdominal discomfort can occur at the beginning of treatment; this is rapidly eliminated by reducing the dose. Overdose can result in diarrhoea. In abuse, loss of electrolytes (primarily potassium).

PRECAUTION

Niprolac should be administered with care to patients who are intolerant to lactulose. The dose used in the treatment of (pre) coma hepaticum is usually much higher and may need to be taken into consideration for diabetics.

CONTRAINDICATION

Hypersensitivity to either galactose and or lactose; galactose-free diet, gastro-cardial symptom complex, suspected intestinal obstruction.

DRUG INTERACTION

There is no significant drug interactions with lactulose. The glycosidic effect of cardiac glycosides can be intensified by potassium deficiency in abuse.

USE IN PREGNANCY AND LACTATION

US FDA Pregnancy Category of Lactulose is B. Studies show that Lactulose has no adverse effects. Decisions regarding use during pregnancy and lactation must be made by registered physician.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

Each amber PET bottle contains 100 ml oral solution.

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.