ANPROLAC SOLUTION 670mg/ml

Clear to pale brownish-yellow viscous liquid.

PHARMACOLOGY:
In the colon lactulose is broken down by colonic bacteria into low-molecular organic acids. These acids lower the pH in the colonic lumen and increase the volume of the colonic contents via an osmotic effect. These effects stimulate peristalsis of the colon and return normal consistency of the stool. Constipation is corrected and the physiological rhythm of the colon is reinstated.
In hepatic encephalopathy (HE), the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect and alteration of bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis. Within this context, however, it should be realized that hyperammonemia alone cannot explain the neuropsychiatric manifestation of HE. The ammonia might, however, serve as a model compound for other nitrogeneous substances.
Lactulose as a prebiotic substance strengthens the growth of health promoting bacteria, like Bifidobacterium and Lactobacillus, whereas potentially pathogenic bacteria, like Clostridium and Escherichia coli may be suppressed.
This may lead to a more favorable balance of the intestinal flora.

PHARMACOKINETICS:
Lactulose is poorly absorbed after oral administration and reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50g or 40-75ml; at higher dosages, a proportion may be excreted unchanged.

COMPOSITION:
Lactulose solution 670mg/ml

INDICATIONS:
- Constipation: regulation of the colonic physiological rhythm
- When soft stool is considered of medical benefit (haemorrhoids, post colonic/anal surgery)
- Hepatic encephalopathy (HE): treatment and prevention of hepatic coma or precoma.

ROUTE OF ADMINISTRATION:
Oral route

DOSAGE/ADMINISTRATION:
You may take Anprolac Solution diluted or undiluted. Take your dose of lactulose in one swallow; do not hold the solution in your mouth for any length of time.
Your doctor will adjust the dosage according to your response to the medicine. If you have been prescribed a single daily dose, always take it at the same time of day, e.g. during breakfast.
During therapy with laxatives it is important for you to drink sufficient amounts of fluids (1.5-2 litres, equal to 6-8 glasses) during the day.

Dosing in constipation or where soft stool is considered of medical benefit:
Anprolac Solution may be taken as a single daily dose or in two divided doses. Your doctor will tell you which frequency to use. Based upon treatment response your doctor may adjust the starting dose to the maintenance dose after a few days. Several (2-3) days of treatment may be needed before treatment effect occurs.

	Anprolac Solution	
	Starting dose daily	Maintenance dose daily
Adults and adolescents	15-45ml	15-30ml
Children (7-14 years)	15ml	10-15ml
Children (1-6 years)	5-10ml	5-10ml
Infants under 1 year	Up to 5ml	Up to 5ml

Dosing in HE (for adults only)
Starting dose: 3 to 4 times daily 30-45ml The dose should be adjusted by your doctor to the maintenance dose to achieve 2 to 3 soft stools per day. The safety and efficacy in children (newborn to 18 years of age) with HE have not been established. No data are available.
Elderly patients and patients with renal or hepatic insufficiency. No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

ADVERSE EFFECTS:
Flatulance may occur during the first few days of treatment. As a rule, it disappears afer a couple of days. Diarrhea and abdominal pain may be experienced if you take a higher dose than instructed. If this occurs, the dosage should be decreased to reflect the recommended dosage.
If you are taking a high dose (normally only with hepatic encephalopathy HE) for an extended period of time, you may experience an electrolyte imbalance (not enough electrolytes in your blood) due to diarrhea.

INTERACTIONS WITH OTHER MEDICAMENTS:
No interaction studies with other medications have been performed.

PRECAUTIONS/WARNINGS:
Consultation of a physician is advised in case of:
- Painful abdominal symptoms of undetermined cause before the treatment is started.
- Insufficient therapeutic effect after several days.

If the desired results are not observed after several days of treatment, consult your doctor. Patients who are intolerant to lactose should take Anprolac Solution with care (because it contains lactose). The dose normally used in constipation should not pose a problem for diabetics. However, the dose used in the treatment of HE is usually much higher and should be taken into consideration for diabetics.
Chronic use of unadjusted doses and misuse can lead to diarrhea and disturbance of the electrolyte balance. Use of laxatives in children should be exceptional and under medical supervision. It should be taken into account that the defaecation reflex could be disturbed during the treatment. You may want to take protective measures, such as using diapers, for your small child.
This product contains lactose, galactose and small amounts of fructose. Therefore, patients with the rare hereditary problems of galactose or frustose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

PREGNANCY AND LACTATION:
Pregnancy :
During pregnancy, no effects to the feotus are anticipated, since systemic exposure of lactulose to the pregnant woman is negligible. Anprolac Solution can be used during pregnancy.
Lactation :
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of lactulose to the breast-feeding woman is negligible. Anprolac Solution can be used during breastfeeding.

CONTRAINDICATIONS:
Do not take Anprolac Solution
- If you are hypersensitive (allergic) to lactulose or to any of the ingredients of Anprolac Solution.
- If you suffer from galactosaemia.
- If you suffer from gastrointestinal obstruction, digestive perforation or risk of digestion perforation.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE:
If you have taken too high a dose you may experience the following symptoms: diarrhea and/or abdominal pain. Under these circumstances, the treatment should be stopped or the dosage reduced sufficiently for the symptoms to subside. Extensive fluid loss (dehydration) secondary to diarrhea or vomiting may require the intake of extra electrolytes. Please ask your doctor or pharmacist for advice.

PHARMACEUTICAL INFORMATION / PACKAGE:

Description ***:*** Clear to pale brownish-yellow viscous liquid.

Packing Size ***:*** ~100 ml (plastic bottle)

Storage ***:*** Store in the original package and in a dry place. Do not store above 30°C. Protect from light. Keep out of reach of children.

Shelf Life ***:*** 3 years from date of manufacturing.

MANUFACTURER & PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

18/03/2016