NOPHALAC SOLUTION 670mg/ml

DESCRIPTION:
Clear, viscous liquid, colourless or pale brownish-yellow with a sweet taste.

COMPOSITION:
Each ml of solution contains 670mg Lactulose

PHARMACODYNAMIC:
Lactulose, a synthetic disaccharide which is the active ingredient of NOPHALAC is metabolized in the colon by the sacchrolytic bacteria producing low molecular weight organic acid mainly lactic acid via bacterial degradation. This lowers the pH of the colon contents with stimulation of peristalsis by promoting the retention of water by an osmotic effect.
In portal systemic encephalopathy (PSE) or (pre)coma hepaticum, 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 the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.

PHARMACOKINETICS:
Lactulose is minimally absorbed after oral administration. It reaches the colon unchanged, where it is metabolized by the colonic bacteria flora. Metabolism is completed at 20-50g or 40-75ml; at higher dosages, a proportion may be excreted unchanged.

INDICATIONS:
Constipation: Regulation of the physiological rhythm of the colon.
Portal systemic encephalopathy (PSE): Treatment and prevention of hepatic coma or precoma.
Where a soft stool is considered of medical benefit (haemorrhoids, after colon/anal surgery)

DOSAGE & ADMINISTRATION:
Lactulose can be taken as a single daily dose or in two divided doses. Dose need to be taken in one swallow. It should not be held in the mouth for length of time.
Dosage will be adjusted to individual needs. NOPHALAC is best taken at the same time each day, preferably at breakfast time.
Nophalac can be taken diluted or undiluted.

ROUTE OF ADMINISTRATION:
Oral administration

Dosing in constipation or where soft stool is considered of medical benefit
<u>Adults</u>
Starting dose: 15-45ml
Maintenance dose: 15-30ml
<u>Children (7-14 years)</u>
Starting dose: 15 ml
Maintenance dose: 10-15ml
<u>Children (1-6 years)</u>
Starting dose: 5-10 ml

Maintenance dose: 5-10 ml
Infant under 1 year
Starting dose: 5 ml
Maintenance dose: 5 ml

Dosing in precoma and coma hepaticum (for adults only)

Starting dose: 30-45ml, three to four times daily.
The maintenance dose should be adjusted so that soft stools are produced 2-3 times daily

The starting dose can be adjusted to the individual after reaching adequate treatment effect (maintenance dose). Several days (2-3 days) of treatment may be needed in some patients before treatment effect occurs.
During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5–2 litres, equal to 6-8 glasses) during the day.

CONTRAINDICATIONS:

Contraindicated in patient with galactosaemia and in cases of gastrointestinal obstruction

SIDE 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 diarrhea may occur. In such a case the dosage should be decreased. If high doses (normally only associated with portosytemic encephalopathy, PSE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhea. Dosage should then be adjusted to obtain two or three formed stools per day.
Gastrointestinal disorders: Flatulence, abdominal pain, nausea and vomiting. If dosed too high, diarrhoea.
Investigations: Electrolyte imbalance due to diarrhoea.

PRECAUTIONS:

Patients who are intolerant to lactose should take NOPHALAC oral solution with care. The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of (pre) coma hepaticum is usually much higher and should be taken into consideration for diabetics. Laxatives (of any kind) should be used when absolutely necessary and only after consulting a doctor. Faecal retention abilities could be disturbed during treatment with NOPHALAC oral solution.
Patience with the rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. It should be taken into consideration that the exoneration reflex could be disturbed during the treatment. In case of insufficient therapeutic effect after several days, consultation of a physician is advised

PREGNANCY & LACTATION:

There is only limited data on pregnant patients taking lactulose. The available data indicates neither malformative nor foeto/neonatal toxicity. The use of lactulose maybe considered during pregnancy if necessary.
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to lactulose is negligible.
Lactulose can be used during breast-feeding.

DRUG INTERACTION:
There is a possibility that nonabsorbable antacids given concurrently may inhibit the desired lactulose-induced drop in colonic pH. Therefore, a possible lack of desired effect of treatment should be taken into consideration before such drugs are given concomitantly with NOPHALAC.

OVERDOSAGE & TREATMENT:
Symptom: diarrhea and abdominal pain
Treatment: cessation of treatment of dose reduction. Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbance
No specific antidote. Symptomatic treatment should be given.

PRESENTATION: HDPE bottles of 60ml, 100ml, 120ml, 200 ml and 500ml.

STORAGE: Store below 30^{o}C

MANUFACTURER AND PRODUCT REGISTRATION HOLDER:
Noripharma Sdn. Bhd. 200701034604 (792633-A)
Lot 5030 Jalan Teratai,
5 ½ Mile off Jalan Meru,
41050 Klang,
Selangor Darul Ehsan, Malaysia.

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