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LACPHAVID ORAL SOLUTION 3.35G / 5ML

VILACxx-0 (MY)

DESCRIPTION
A clear, viscous, colourless to pale brownish-yellow liquid.

COMPOSITION
Each 5 ml contains: Lactulose 3.35g

PHARMACODYNAMICS
Lactulose is broken down in the colon by colonic bacteria into low molecular organic acids. These acids lowers the pH in the colonic lumen and increases the volume of colonic contents via an osmotic effect. These effects stimulates the peristalsis of the colon and return the consistency of the stool. The constipation is cleared and the physiological rhythm of the colon is reinstated.

In hepatic encephalopathy (HE), the effect has been attributed to the 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 poorly absorbed after oral administration and it would reach the colon unchanged. In the colon, lactulose is then metabolised by the colonic bacterial. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged.

INDICATION
- 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

CONTRAINDICATIONS
Lacphavid is contraindicated to those who has:
- Hypersensitivity to the active substance, Lactulose.
- Galactosaemia
- Gastro-intestinal obstruction, digestive perforation or risk of digestive perforation.

WARNINGS AND PRECAUTIONS
- Painful abdominal symptoms of undetermined cause should be evaluated to exclude undiagnosed perforation or obstruction or undiagnosed disease/condition that predisposes to either before the treatment with Lacphavid is started.
- In case of insufficient therapeutic effect after several days, the dose and/or additional measures should be re-considered.
- 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.
- The dose used in the treatment of HE is usually much higher and consideration may need to be taken for diabetics.
- Chronic use of unadjusted doses and misuse of Lacphavid can lead to diarrhoea and disturbance of the electrolyte balance.
- It should be taken into account that the defaecation reflex could be disturbed during the treatment.
- This product contains lactose, galactose and small amounts of fructose. Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- In the paediatric population, the use of laxatives in children should be exceptional and under the medical supervision.

PREGNANCY AND LACTATION
Pregnancy
There should not be any effects during pregnancy since systemic exposure to lactulose is negligible. Lacphavid can be used during pregnancy.

Breast-feeding
There should not be any effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to lactulose is negligible. Lacphavid can be used during breast-feeding.

Fertility
No effects are to be expected since systemic exposure to lactulose is negligible.

MAIN SIDE/ADVERSE EFFECTS
Flatulence may occur during the first few days of treatment and it would disappear after a couple of days. When higher dosage than the instructed dosage are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

If high doses (normally associated with hepatic encephalopathy, HE) are used for an extended period of time, patient may experience an electrolyte imbalance due to diarrhoea. Dosage should then be adjusted to obtain two or three formed stools per day.

Tabulated List of Adverse Reactions
The following undesirable effects have been observed with the below indicated frequencies: very common (≥1/10); common (≥ 1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (<1/10,000).

	FREQUENCY CATEGORY			
	Very Common	Common	Uncommon	Rare
Gastrointestinal Disorders	Diarrhoea	Flatulence, Abdominal Pain, Nausea, Vomiting		
Investigations			Electrolyte imbalance due to diarrhoea	

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BACK

Paediatric Population
The safety profile in children is expected to be similar as in adults.

Lactulose has none or negligible influence on the ability to drive and use machines.

DRUG INTERACTIONS
No interaction studies have been performed.

OVERDOSE AND TREATMENT
If the dose is too high, diarrhoea and abdominal pain may occur.

For the treatment of overdose, cessation of treatment or dose reduction should be considered. Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

There is no specific antidote for the overdose of lactulose. Symptomatic treatment should be given.

DOSAGE AND ADMINISTRATION
For oral use only.

Lacphavid may be administered diluted or undiluted. Each dose may, if necessary, be taken with water or fruit juices.

Each dose of Lacphavid should be swallowed in one and should not be kept in the mouth for an extended period of time.

All dosage should be adjusted to the needs of the individual.

In case of single daily dose, Lacphavid should be taken at the same time, e.g. during breakfast.

During the therapy with Lacphavid, which is a type of laxatives, it is recommended to drink sufficient amounts of fluids (1.5-2 litres, equal to 6-8 glasses) during the day.

Dosing in Constipation
Lacphavid may be given as a single daily dose or in two divided doses.

After a few days, the starting dosage may be adjusted to the maintenance dose based upon treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

	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 Hepatic Encephalopathy (for adults only)
Starting dose: 3 to 4 times daily, 30-45ml (6-9 x 5ml spoonful). This dose may be adjusted to the maintenance dose to achieve two or three soft stools each day.

Paediatric Population
The safety and efficacy in children (newborn to 18 years of age) with Hepatic Encephalopathy have not been established.

Elderly Patients and Patients with Renal or Hepatic Insufficiency
No special dosage recommendations as systemic exposure to lactulose is negligible.

Note: The information given here is limited. For further information consult your doctor or pharmacists.

Storage:
Store below 30°C

Presentation/Packing:
Oral solution 3.35g/5ml x 60ml, 100ml, 120ml, 200ml.

Product Registration Holder / Marketing Authorization Holder / Product Owner / Manufactured by:
Hovid Berhad
121, Jalan Tunku Abdul Rahman
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Date of revision: May 2023