

LACPHAVID ORAL SOLUTION 3.35G/5ML

Lactulose Solution (3.35g/5ml)

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What Lacphavid Oral Solution 3.35g/5ml is used for

Lacphavid is used to treat constipation (infrequent bowel movements, hard and dry stools) and used when soft stool is considered of medical benefit (haemorrhoids, post colonic/anal surgery). Lacphavid is also used to treat and prevent hepatic coma or precoma in hepatic encephalopathy patient (a liver disease causing confusion, tremor, and decreased level of consciousness).

How Lacphavid Oral Solution 3.35g/5ml works

Lacphavid contains a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

Before you use Lacphavid Oral Solution 3.35g/5ml

- When you must not use it

Do not take Lacphavid if:

- You are allergic (hypersensitive) to lactulose
- You have a rare problem called 'galactosaemia' (a metabolic disorder that affects an individual's ability to metabolize the sugar galactose properly).
- You have a blockage caused by anything else but normal constipation, digestive perforation or risk of digestive perforation.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist before taking Lacphavid.

- Before you start to use it

Talk to your doctor or pharmacist before taking Lacphavid if you suffer from any medical conditions or illnesses, in particular:

- if you suffer from unexplained tummy ache
- if you are unable to digest milk sugar (lactose intolerant)
- if you have diabetes

You should not take Lacphavid if you suffer from:

- galactose or fructose intolerance
- Lapp lactase deficiency
- glucose-galactose malabsorption

If you have diabetes and are treated for hepatic encephalopathy, your dose of Lacphavid will be higher. This high dose contains a large amount of sugar. Therefore, your doctor may recommend that you need to adjust

the dose of your anti-diabetic medicine.

Chronic use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolytes balance.

During the treatment with laxatives, you should drink sufficient amounts of fluids (approx. 2 litres/day, equal to 6-8 glasses).

Children

The use of laxatives in children should be exceptional and under the medical supervision.

If you take Lacphavid for several days and there is no improvement in your condition or if your symptoms worsen, please contact your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Lacphavid Oral Solution 3.35g/5ml

- How much to use

- You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 6-8 glasses throughout the day).
- Swallow each dose of Lacphavid immediately. Do not keep it in your mouth for long periods.
- If Lacphavid is to be taken only once daily, it should be taken at the same time (eg. During breakfast).

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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.

Adults and Adolescents

Starting Dose: 15ml – 45ml

Maintenance Dose: 15ml – 30ml

Children (7-14 years)

Starting Dose: 15ml

Maintenance Dose: 10ml - 15ml

Children (1-6 years)

Starting Dose: 5ml – 10ml

Maintenance Dose: 5ml – 10ml

Infants under 1 year

Starting Dose: up to 5ml

Maintenance Dose: up to 5ml

Dosing in Hepatic Encephalopathy (for adults only)

Starting dose: 3 to 4 times daily, 30ml-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.

- When to use it

Lacphavid can be taken with or without food. There are no restrictions on what you can eat or drink.

- How long to use it

Continue taking Lacphavid for as long as your doctor or pharmacist recommends.

However, if you have taken Lacphavid for several days and there is no improvement in your condition or if your symptoms worsen, please contact your doctor.

- If you forget to use it

If you forget a dose of Lacphavid, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take more Lacphavid than you should, stop taking Lacphavid and talk to a doctor or pharmacist.

You may have diarrhoea, loss of electrolytes and abdominal pain.

While you are using Lacphavid Oral Solution 3.35g/5ml

- Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Lacphavid can be used during pregnancy and when

breast-feeding if necessary. No effects on fertility are to be expected.

- Things you must not do

Do not stop or change the treatment before talking to your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Lacphavid to anyone else, even if they have the same symptoms or condition as you.

Do not take more than the recommended dose unless your doctor or pharmacist tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- Things to be careful of

Lacphavid has no or negligible influence on your ability to drive safely or use machines.

Side effects

Like all medicines, Lacphavid can cause side effects, although not everybody gets them.

The following side effects may occur with consumption of Lacphavid:

Very common (may affect more than 1 in 10 people)

- Diarrhoea

Common (may affect up to 1 in 10 people)

- Flatulence (wind)
- Nausea (feeling sick)
- Vomiting

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- Abdominal pain

Uncommon (may affect up to 1 in 100 people)

- Electrolyte imbalance due to diarrhoea

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

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

- Inactive ingredients

Not applicable

- MAL number:

MAL21076023XZ

Manufacturer

Hovid Berhad

121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Product Registration Holder

Hovid Berhad

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30010 Ipoh, Perak, Malaysia.

Date of revision

23/05/2023

Serial Number

NPRA(R2)/21/016

Storage and Disposal of Lacphavid Oral Solution 3.35g/5ml

- Storage

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

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

- Ingredients

- Active ingredient(s)

Each 5ml contains Lactulose 3.35g