

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Laevolac, Solution

Active ingredient

lactulose 670 mg/ml

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, contact your doctor or pharmacist.

Take this medicine according to the instructions in the section about dosage in this leaflet. Consult your pharmacist if you need further information. Contact your doctor if the disease symptoms get worse or do not improve after 3 days.

1. What is this medicine intended for?

Laevolac is indicated for:

- Treatment of constipation.
- Treatment of acute and chronic hepatic encephalopathy (hepatic coma).

Therapeutic group: Osmotic laxatives.

Laevolac contains a laxative called lactulose, which softens the stool and enables easier stool passage by drawing water into the intestines. This substance is not absorbed into the body.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to lactulose or to any of the other ingredients in this medicine (see section 6 'Additional information').
- You suffer from galactosemia (a severe genetic disorder that does not enable galactose digestion).
- You suffer from inflammatory bowel disease (such as Crohn's disease or ulcerative colitis), bowel obstruction (unrelated to your constipation), gastrointestinal ulcers or a risk of developing gastrointestinal ulcers, abdominal pain for unknown reason.

Special warnings about using this medicine

Consult your doctor or pharmacist before taking lactulose.

Before treatment with Laevolac, tell your doctor if:

- You suffer from gastro-cardiac syndrome (**Roemheld syndrome**).
- If you experience symptoms of abdominal distention or flatulence after using **Laevolac**, **stop the treatment and consult your doctor**.
In these cases, your doctor will supervise the treatment more carefully.

Additional warnings

- Prolonged use of inappropriate dosage (causing 2-3 soft stools per day) or misuse may lead to diarrhea and impairment of electrolyte balance in the body.
- If you suffer from hepatic encephalopathy, avoid taking **Laevolac** concomitantly with other laxatives, since this may interfere with the adjustment of **Laevolac** dosage for you.
- It is not recommended to use **Laevolac** for more than 2 weeks continuously without consulting your doctor.

- If you are an elderly patient or a patient in bad general condition, and you take **Laevolac** for a period longer than 6 months, your doctor will regularly check your blood electrolyte levels.
- **Laevolac** may contain residues of sugars (due to the manufacturing process). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Children and adolescents:

For treatment of hepatic encephalopathy: **Laevolac** is not intended for this indication in children and adolescents below the age of 18 as there is not enough information about this population.

For treatment of constipation: It is generally not recommended to give **Laevolac** to infants and young children, as it can disturb the normal reflexes for passing stools.

In special circumstances, your doctor may prescribe **Laevolac** for a child, toddler or baby. In these cases, your doctor will supervise the treatment carefully.

Use of a medicine containing lactulose should be done with caution in infants and young children with autosomal recessive hereditary fructose intolerance.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

- **Laevolac** intake may increase the loss of potassium when taken with medicines causing loss of potassium, e.g. thiazides, steroids and amphotericin B.
- Taking **Laevolac** concomitantly with cardiac glycosides may increase the effect of the glycosides due to potassium deficiency.

- As the dosage of **Laevolac** increases, the **pH** value in the colon decreases. Therefore, medicines which are decomposed and released in the colon in a **pH**-dependent manner may not be decomposed and released (e.g. medicines for treatment of Crohn's disease such as **5-ASA**), and may thus be inactive.

Using this medicine and food

Laevolac can be taken with or without food. There is no limitation regarding drinking and eating.

During treatment with **Laevolac**, you should drink a sufficient amount of fluids (about 2 liters per day, equivalent to 6-8 glasses).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you are pregnant or plan to become pregnant, consult your doctor or pharmacist before taking the medicine.

Driving and operating machines

Laevolac does not affect the ability to drive or operate machines.

Important information about some of this medicine's ingredients

Laevolac may contain sugar residues from the manufacturing process, lactose, galactose, epilactose, tagatose or fructose.

Therefore, if you have been told that you have an intolerance to some sugars, consult your doctor before taking **Laevolac**.

15 ml of **Laevolac** contains **42.7 KJ** equivalent to **10.2 kcal**. The dosage may need to be adjusted for patients with diabetes.

3. How to use this medicine?

- Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Take **Laevolac** at the same time every day. The daily dose may be taken once daily, for example during breakfast, or divided into up to three doses during the day.

- Swallow the medicine immediately upon intake, do not keep it in your mouth.
- You can take **Laevolac** as is or diluted with a beverage. Use the measuring cup supplied with the bottle.

Hepatic encephalopathy (hepatic coma)

The recommended dosage is usually:

Adults (including elderly): Initial dose 30-50 ml 3 times per day.

Subsequently the dosage should be adjusted until the patient has 2-3 soft stools per day.

Children: The medicine is not intended for this indication in children and adolescents below the age of 18 years since there is no sufficient data on this population.

Constipation

Use the medicine according to the instructions listed below or according to your doctor's or pharmacist's instructions. The recommended dosage is usually:

| Age | Initial daily dose for 2-3 days | Daily dose for further treatment |
|---|---------------------------------|----------------------------------|
| Adults and adolescents over 14 years of age (including elderly) | 15-30 ml | 15-30 ml |
| Children and babies | | |
| Age 7-14 years | 15 ml | 10-15 ml |
| Age 1-6 years | 5-10 ml | 5-10 ml |
| Under 1 year of age | up to 5 ml | up to 5 ml |

During the period of use, it is recommended to drink plenty of fluids, at least 1.5-2 liters per day (6-8 glasses during the day), which will help soften the stool.

Due to the special activity of lactulose, 48 hours may pass until the effect of the medicine becomes evident.

If diarrhea is caused, reduce the dosage.

Children: In these cases, your doctor will supervise the treatment carefully.

Duration of treatment

Adopt the treatment duration according to the symptoms.

If there is no improvement in constipation after several days of treatment with **Laevolac**, consult your doctor.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, you or your child may experience diarrhea and abdominal pain. Immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

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

If you stop taking Laevolac prior to treatment completion, you may experience no relief in your condition.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Laevolac** may cause side effects in some users. Do not be alarmed by this list of side effects; you

may not experience any of them.

Very common side effects - affect more than one in ten users:

- Abdominal distention, flatulence, especially during the first few days of treatment. This effect usually resolves after several days of treatment.
- Diarrhea and abdominal pain; these effects usually occur upon intake of a dosage higher than that recommended by your doctor.

Common side effects - affect 1-10 in 100 users:

- Nausea.
- Vomiting.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Allergic reactions.
- Rash.
- Itching.
- Hives.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the outer package. The expiry date refers to the last day of that month.

Storage conditions

- Store at a temperature below 25°C.
- Keep the bottle tightly closed.
- The medicine can be used for 12 months after opening, and no later than the expiry date stated on the package.

6. Additional information

- There are no additional ingredients other than the active ingredient lactulose.
- Each 5 ml of **Laevolac** contains 3.3 g lactulose.

What the medicine looks like and contents of the pack:

A clear, viscous, colorless or pale brown-yellowish solution. Available in plastic bottles containing 300 ml or 500 ml with a plastic measuring cup. Not all pack sizes may be marketed.

- **Registration holder's name and address:** Megapharm Ltd., 15 Hatidhar street, Ra'anana, Israel.
- **Manufacturer's name and address:** Fresenius-Kabi, Graz, Austria.
- This leaflet was revised in March 2024 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 115-98-29714.