

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription.

Avilac Syrup

Each 100 ml contain: Lactulose 66.7 g.

Inactive and allergenic ingredients in the preparation: see in section 2 'Important information about some of the ingredients of the medicine' and in section 6 in the leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use this medicine according to the dosage instructions in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if signs of the illness (symptoms) worsen or if they do not improve after a few days.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of constipation (infrequent bowel movements, hard and dry stools) and treatment of acute and chronic hepatic encephalopathy (a

liver disease causing confusion, tremor, reduced consciousness). Hepatic encephalopathy can lead to hepatic coma.

Therapeutic group: Osmotic laxatives.

Avilac Syrup is a medicine that contains a laxative ingredient called lactulose that makes the stool softer and easier to pass by drawing water into the bowel. The ingredient is not absorbed into your body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient lactulose or to any of the additional ingredients contained in the medicine (for a list of the inactive ingredients, see section 6 in the leaflet).
- You suffer from a rare problem of galactose intolerance (galactosemia).
- You suffer from digestive tract obstruction that is not the result of normal constipation, digestive tract perforation or are at risk of a digestive tract perforation.

Do not take Avilac Syrup if any of the aforementioned apply to you. If you are uncertain, consult with the doctor or pharmacist before using Avilac Syrup.

Special warnings regarding use of the medicine:

- Prolonged use may cause dependency on laxatives.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.

Before treatment with Avilac, tell the doctor or pharmacist if:

- You are suffering from unexplained abdominal pain.
- You are unable to digest milk sugar (lactose intolerance).
- You have diabetes.

Do not take Avilac if you are suffering from:

- Intolerance to galactose or fructose.
- A deficiency in the Lapp lactase enzyme.
- Impaired absorption of glucose-galactose.

If you have diabetes and are being treated for hepatic encephalopathy, your Avilac dose will be higher. This high dose contains a large amount of sugar; therefore, your doctor will recommend changing the dosage of the medicines you are taking for diabetes accordingly.

Chronic use of unadjusted dosages (more than 2-3 soft stools per day) or misuse may lead to diarrhea and disturbance of the electrolyte balance. During use of laxatives, it is recommended to drink a sufficient amount of fluids (approximately 2 liters per day, equal to 6-8 glasses during the day), which will help soften the stools.

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

Children and adolescents

In special cases, the doctor may prescribe Avilac for a child, toddler or baby. These cases will be monitored under close supervision of the doctor.

For treatment of constipation: Use of Avilac Syrup in smaller children and toddlers should only be as per a doctor's instructions, since the medicine may influence the normal reflexes that act when passing stools.

Tests and follow-up

During treatment with the medicine, you may also be referred for a blood electrolytes test. If you are taking a high dosage for long-term treatment of hepatic coma, you may suffer from an electrolyte imbalance (blood electrolyte deficiency), caused as a result of diarrhea.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Use of Avilac and food

Avilac can be taken with or without food. There are no limitations regarding the type of food and drink.

Pregnancy, breastfeeding and fertility

If you are pregnant, might be pregnant or are breastfeeding, tell the doctor or pharmacist before using the medicine. If necessary, Avilac can be used during pregnancy and when breastfeeding. No effects on fertility are expected.

Driving and operating machinery

Avilac Syrup has a negligible or no effect on your ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

The medicine may contain small amounts of sugars such as: fructose, galactose, lactose. If the medicine comes into contact with the teeth and

is given for long-term use, it may damage the teeth.

If you have been told by the doctor that you have a sensitivity to certain sugars, consult him before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the medicine. The usual dosage is generally:

Hepatic encephalopathy (hepatic coma)

Adults (including the elderly): Starting dose 30-50 ml, 3 times a day. After that, the dosage should be adjusted until 2-3 soft stools per day are achieved.

Use in children: There is no available information for use in children (from newborns up until the age of 18).

Constipation

Age	Starting daily dose for 3 days	Daily dose for continued treatment
Adults (including the elderly)	15-30 ml	15-30 ml
Children and infants 7-14 years of age	15 ml	10-15 ml
1-6 years of age	5-10 ml	5-10 ml
Under one year	up to 5 ml	up to 5 ml

It takes Avilac between two and three days to begin to act. After this time, you will be able to reduce the dosage in accordance with your needs.

Do not exceed the recommended dose.

Duration of treatment

If there is no improvement in your condition or if your symptoms worsen after a few days of treatment with Avilac, contact the doctor.

Method of administration

You may use a measuring spoon or cup to take Avilac. Avilac can be mixed with fruit juice or water. It is recommended to drink a large amount of fluid (approximately 6-8 cups over the day). Swallow the dose of medicine immediately and do not hold it in your mouth, since the sugar content in it may damage the teeth, particularly if Avilac is taken for long periods.

If you accidentally took a higher dosage, stop taking Avilac and consult the doctor or pharmacist. You may suffer from diarrhea and abdominal pain. If you took an overdose, or if a child or anyone else has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the designated time, do not worry. Take the next dose at the usual time and consult the doctor. Do not take a double dose to compensate for the forgotten dose.

If you stop taking the medicine

Before stopping or changing the treatment, discuss with the doctor or pharmacist about the consequences.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Avilac may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects – occur in more than one user in 10: diarrhea.

Common side effects – occur in up to one user in 10: flatulence (wind), nausea, vomiting, abdominal pain.

Uncommon side effects – occur in up to one user in 100: blood electrolyte imbalance caused as a result of diarrhea.

Bloating may occur in the first days of treatment. It usually passes after a few days.

When dosages higher than instructed are used, abdominal pain and diarrhea may occur. In such cases, reduce the dosage.

At high, long-term dosages (generally for treatment of hepatic coma), you may suffer from an electrolyte imbalance due to diarrhea.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package and bottle. The expiry date refers to the last day of that month.

Storage conditions: Store in a cool place, below 25°C, in the original package, standing upright.

After first opening, it can be used for 12 months, but no later than the expiry date.

6. FURTHER INFORMATION

In addition to the active ingredient, Avilac Syrup may contain small amounts of sugars such as:

Tagatose, fructose, galactose, epilactose, lactose

What the medicine looks like and the contents of the package: Avilac is a viscous, clear to brownish-yellowish liquid that comes in a white or brown bottle with a white cap and contains 300 ml medicine.

Manufacturer and registration holder: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 3175.25187