

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Bylvay 200 micrograms hard capsules

Bylvay 400 micrograms hard capsules

Bylvay 600 micrograms hard capsules

Bylvay 1,200 micrograms hard capsules

The active ingredient and its quantity:

Bylvay 200 mcg hard capsules:

Each hard capsule contains 200 mcg odevixibat (as sesquihydrate)

Bylvay 400 mcg hard capsules:

Each hard capsule contains 400 mcg odevixibat (as sesquihydrate)

Bylvay 600 mcg hard capsules:

Each hard capsule contains 600 mcg odevixibat (as sesquihydrate)

Bylvay 1,200 mcg hard capsules:

Each hard capsule contains 1,200 mcg odevixibat (as sesquihydrate)

Inactive ingredients and allergens in the preparation – see section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. PFIC is a liver disease caused by build-up of bile acids (cholestasis) that gets worse over time and is sometimes accompanied by severe itching.
- For the treatment of cholestatic itch in patients aged 12 months or older with Alagille syndrome (ALGS). This medicine increases the removal of bile acids from the body. Bile acids are components of the digestive fluid called bile, which is produced by the liver and secreted into the intestines. The active ingredient, odevixibat, blocks the mechanism that normally reabsorbs the bile acids from the intestines after they have done their job. This allows them to pass out of the body via the stool.

Therapeutic class: other medicines for bile treatment.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to odevixibat or to any of the other ingredients this medicine contains (see section 6 “Additional information”).

Special warnings regarding the use of the medicine

Before treatment with Bylvay, tell the doctor if:

- You have been diagnosed with a complete absence or lack of function of bile salt export pump protein.
- You have severely reduced liver function.
- You have reduced stomach or bowel motility, or reduced circulation of bile acids between the liver, bile and small intestine, due to medicines, surgical procedures or diseases other than PFIC, since these may reduce the effect of the medicine.

Talk to the doctor if you develop diarrhea while taking the medicine. Drinking sufficient liquid is recommended to patients with diarrhea to prevent dehydration.

Children

Bylvay is not intended for the treatment of PFIC in babies under the age of 6 months because there is no information regarding the safety and efficacy of using this medicine in babies under the age of 6 months.

Bylvay is not intended for the treatment of ALGS in babies under the age of 12 months because there is no information regarding the safety and efficacy of using this medicine in babies under the age of 12 months.

Tests and follow-up

Increased levels of liver enzymes may be found in liver function tests of patients receiving the medicine. Before treatment with Bylvay, your doctor will check your liver function to assess how your liver is working. Your doctor will perform routine tests to monitor liver function.

Before and during treatment, your doctor may order blood tests to monitor the levels of vitamin A, D and E and a value called INR which measures your risk of bleeding.

Drug interactions

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

Treatment with this medicine may affect the absorption of fat-soluble vitamins such as vitamin A, D and E, and certain medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with a doctor before taking this medicine.

Bylvay is not recommended during pregnancy and in women of childbearing age not using contraception. It is not known whether the medicine can pass into breast milk and affect the baby. Your doctor will help you decide whether to stop breastfeeding or avoid treatment with Bylvay, considering the benefit of breastfeeding to the baby against the benefit of the medicine to the mother.

Driving and operating machinery

Bylvay has no effect or negligible effect on the ability to drive or the ability to operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Treatment must be started and supervised by a doctor experienced in the treatment of progressive liver disease with reduced bile flow.

The dosage and treatment regimen will be determined only by the doctor. The dosage of Bylvay is based on your weight. The doctor will determine the appropriate number and strength of capsules for you.

The recommended dosage for treatment of PFIC in patients aged 6 months and above is:

- 40 micrograms odevixibat per kilogram body weight once daily.
- If the medicine is not working well enough after 3 months, the doctor may increase the dosage to 120 micrograms odevixibat per kilogram body weight (up to a maximum of 7,200 micrograms once daily).

The recommended dosage for treatment of ALGS in patients aged 12 months and above is:

- 120 micrograms odevixibat per kilogram body weight once daily.

There is no difference in the dosage recommended for adults.

Do not exceed the recommended dose.

Method of use

Take the capsules once daily in the morning with or without food.

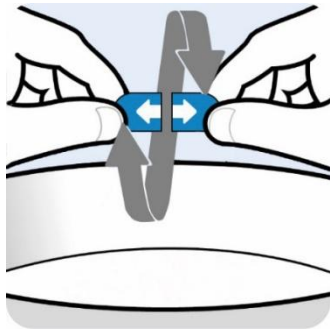
You can either swallow the capsules whole with a glass of water or open them and sprinkle their content on food.

The larger 200 and 600 micrograms capsules are intended to be opened and sprinkled on food, but can be swallowed whole.

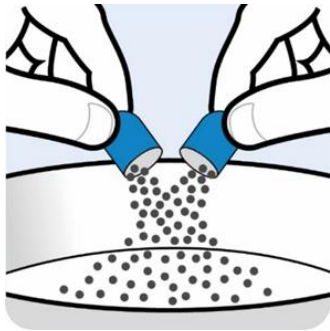
The smaller 400 and 1,200 micrograms capsules are intended to be swallowed whole, but can be opened and their content sprinkled on food.

Instructions for opening the capsules and sprinkling their content on food:

- Place a small amount of soft food in a bowl (2 tablespoons/30 ml of yoghurt, applesauce, banana or carrot puree, chocolate pudding, rice pudding or oatmeal porridge). The food should be at or below room temperature.



- Hold the capsule horizontally at both ends and twist in opposite directions.



- Pull apart to empty the content into the bowl of soft food.
- Gently tap the capsule to ensure that all pellets come out.
- Repeat the previous step if the dose requires more than one capsule.



- Gently mix the content of the capsule into the soft food.

- Take the entire dose immediately after mixing. Do not store the mixture for future use.
- Drink a glass of water after taking the dose.
- Dispose of the empty capsules.

If the medicine does not improve your condition after 6 months of continuous daily treatment, the doctor will recommend an alternative treatment.

If you accidentally took a higher dosage

Tell the doctor if you think that you took too much of the medicine.

Possible symptoms of an overdose are diarrhea, stomach and bowel problems.

If you took an overdose or if a child accidentally swallowed this medicine, refer immediately to a doctor or to a hospital emergency room and take the package of the medicine with you.

If you forgot to take the medicine

Do not take a double dose in order to compensate for a forgotten dose. Take the next dose at the usual time.

If you stop taking the medicine

Do not stop taking the medicine without consulting the doctor first.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

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

Side effects may occur in the following frequencies:

Very common side effects (may occur in more than 1 out of 10 people)

- Increased level of the liver enzyme alanine transaminase (ALT)
- Increased level of bilirubin in the blood
- Vitamin D deficiency
- Diarrhea, including diarrhea with bloody stool, soft stools
- Abdominal pain
- Vomiting

Common side effects (may occur in up to 1 out of 10 people)

- Enlarged liver
- Increased level of the liver enzyme aspartate aminotransferase (AST)
- Vitamin E deficiency
- Hematoma
- Weight loss

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

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions:
Store at a temperature below 25°C.
Store in the original package to protect from light.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

In the capsule content:

Microcrystalline cellulose (MCC) spheres 700

Hypromellose 3mPa.s

In the capsule shell:

Bylvay 200 mcg and Bylvay 600 mcg hard capsules

Hypromellose

Titanium dioxide

Yellow iron oxide (E172)

Bylvay 400 mcg and 1,200 mcg hard capsules

Hypromellose

Titanium dioxide

Yellow iron oxide (E172)

Red iron oxide (E172)

Printing ink

Shellac glaze in ethanol

Black iron oxide

N-butyl alcohol

Isopropyl alcohol

Propylene glycol

Ammonia hydroxide 28%

What does the medicine look like and what are the contents of the package?

Bylvay hard capsules are packed in a plastic bottle with a tamper evident, child resistant polypropylene cap.
Size of the package: 30 hard capsules.

Bylvay 200 micrograms hard capsules:

Size 0 capsules, the cap of the capsule is opaque ivory and the body of the capsule is opaque white, imprinted with "A200" in black ink.

Bylvay 400 micrograms hard capsules:

Size 3 capsules, the cap of the capsule is opaque orange and the body of the capsule is opaque white, imprinted with "A400" in black ink.

Bylvay 600 micrograms hard capsules:

Size 0 capsules, the cap and the body of the capsule are opaque ivory, imprinted with "A600" in black ink.

Bylvay 1,200 micrograms hard capsules:

Size 3 capsules, the cap and the body of the capsule are opaque orange, imprinted with "A1200" in black ink.

Name and address of the license holder:

Medison Pharma Ltd., 10 Hashiloach St., P.O. Box 7090, Petach Tikva.

Revised in June 2025

Registration number of the medicine in the national drug registry of the Ministry of Health:

Bylvay 200 micrograms hard capsules: 171-41-37197-99

Bylvay 400 micrograms hard capsules: 171-42-37198-99

Bylvay 600 micrograms hard capsules: 171-43-37199-99

Bylvay 1,200 micrograms hard capsules: 171-44-37200-99