

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

This 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

Active ingredient and its quantity:

Bylvay 200 mcg hard capsules:

Each hard capsule contains 200 micrograms odevixibat (as sesquihydrate).

Bylvay 400 mcg hard capsules:

Each hard capsule contains 400 micrograms odevixibat (as sesquihydrate).

Bylvay 600 mcg hard capsules:

Each hard capsule contains 600 micrograms odevixibat (as sesquihydrate).

Bylvay 1,200 mcg hard capsules:

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

Inactive ingredients and allergens - see 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, consult your doctor or pharmacist.

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

1. What is the medicine intended for?

Bylvay is indicated 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 often accompanied with severe itching.

This medicine increases the excretion 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 in the stool.

Therapeutic group: other drugs for bile therapy

2. Before using the medicine

X Do not use this medicine if:

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

Special warnings about using this medicine

Talk to your doctor before taking Bylvay 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 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 your doctor if you develop diarrhoea while taking this medicine. Drinking sufficient liquid is recommended in patients with diarrhoea to prevent dehydration.

Children

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

Test and follow-up

Increased levels in liver function tests can occur in some patients receiving this medicine. Assessment of liver function is recommended for all patients prior to Bylvay treatment. Your doctor may recommend more frequent monitoring if you have elevated liver function test results.

Your doctor may recommend assessment of Vitamin A, D and E blood levels and the blood clotting value called INR prior to and during Bylvay treatment.

Drug interactions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescription medications and nutritional supplements.

Treatment with this medicine may affect the absorption of fat-soluble vitamins such as Vitamin A, D and E, and some medicines, including oral contraceptives.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Bylvay is not recommended during pregnancy and in women of childbearing potential not using contraception. Use of a barrier contraceptive method (such as a condom) is recommended since the uptake of lipophilic oral contraceptives may be affected by this medicine.

It is not known if this medicine can pass into breast milk and affect the baby. Your doctor will help you to decide whether to stop breast-feeding or avoid Bylvay treatment, considering the benefit of breast-feeding to the baby versus the benefit of this medicine to the mother.

Driving and using machines

Bylvay has no or negligible influence on the ability to drive or capacity to use machinery.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dose or how to take this medicine.

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

The dose and the method of administration will be determined only by your doctor. The dose of Bylvay is based on your weight. Your doctor will work out the right number and strength of capsules for you to take.

The recommended dose is

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

No dose differences are recommended for adults.

Do not exceed the recommended dose.

Method of use

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

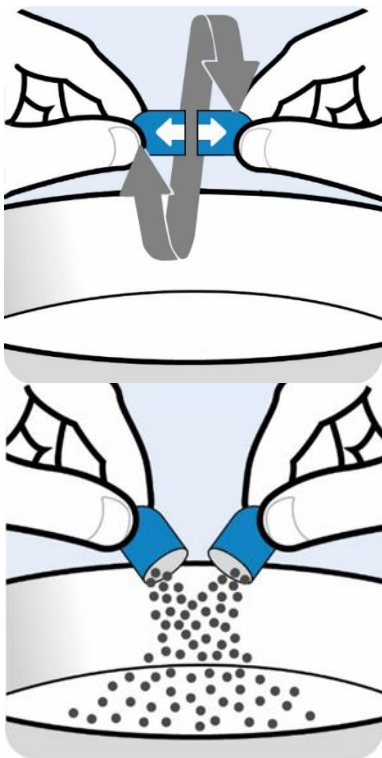
All capsules can be either swallowed whole with a glass of water or opened and sprinkled on food.

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

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

Instructions to open capsules and sprinkle the contents on food:

- Place a small amount of soft food into a bowl (2 tablespoons/30 mL of yoghurt, apple sauce, banana or carrot puree, chocolate pudding, rice pudding or oatmeal porridge). Food should be at or below room temperature.



- Hold the capsule horizontally at both ends, twist in opposite directions.
- Pull apart to empty the contents 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 contents 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 following the dose.
- Dispose of the empty capsule shells.

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

If you have accidentally taken a higher dose

Tell your doctor if you think you have taken too much Bylvay.

Possible overdose symptoms are diarrhoea, stomach and bowel problems.

If you have accidentally taken a higher dose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking this medicine

Do not stop taking this medicine without first discussing with your doctor.

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

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 any further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. Side effects

Like with all medicines, this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects may occur with the following frequency:

common side effects (may affect up to 1 in 10 people)

- diarrhoea, including diarrhoea with bloody stool, soft stools
- abdominal (belly) pain
- enlarged liver

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 of 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, or by the following link:
<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instructions from the doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage Conditions:
Do not store above 25 °C.

Store in the original package to protect from light.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Capsule content

Microcrystalline cellulose (MCC) spheres 700
Hypromellose 3mPa.s

Capsule shell

Bylvay 200 micrograms and 600 micrograms hard capsules
Hypromellose
Titanium dioxide
Yellow iron oxide (E172)

Bylvay 400 micrograms and 1,200 micrograms 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 the medicine looks like and contents of the pack:

Bylvay hard capsules are packed in a plastic bottle with a tamper evident, child resistant polypropylene closure. Pack size: 30 hard capsules.

Bylvay 200 micrograms hard capsules:

Size 0 capsules with ivory opaque cap and white opaque body; imprinted "A200" with black ink.

Bylvay 400 micrograms hard capsules:

Size 3 capsules with orange opaque cap and white opaque body; imprinted "A400" with black ink.

Bylvay 600 micrograms hard capsules:

Size 0 capsules with ivory opaque cap and body; imprinted "A600" with black ink.

Bylvay 1,200 micrograms hard capsules:

Size 3 capsules with orange opaque cap and body; imprinted "A1200" with black ink.

Registration holder's name and address:

Medison Pharma Ltd., 10 Hashiloach St., POB 7090, Petach Tikva.

Manufacturer's name and address:

Albireo AB
Arvid Wallgrens backe 20
413 46 Göteborg
Sweden

Approved in January 2023

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

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

Bylvay 200 mcg, 400 mcg, 600 mcg, 1200 mcg-PIL-1222-V2