Package leaflet: Information for the patient

Bylvay 200 micrograms hard capsules
Bylvay 400 micrograms hard capsules
Bylvay 600 micrograms hard capsules
Bylvay 1 200 micrograms hard capsules
odevixibat

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bylvay is and what it is used for
2. What you need to know before you take Bylvay
3. How to take Bylvay
4. Possible side effects
5. How to store Bylvay
6. Contents of the pack and other information

1. What Bylvay is and what it is used for

Bylvay contains the active substance odevixibat. Odevixibat is a medicine which increases the removal of substances called 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. Odevixibat blocks the mechanism that normally reabsorbs them from the intestines after they have done their job. This allows them to pass out of the body in the stool.

Bylvay is used to treat 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.

Bylvay is also used to treat itching caused by bile build-up in patient aged 6 months or older who have Alagille syndrome (ALGS).

2. What you need to know before you take Bylvay

Do not take Bylvay

- if you are allergic to odevixibat or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Bylvay if you have:
- been diagnosed with a complete absence or lack of function of bile salt export pump protein

- severely reduced liver function
- 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 and ALGS, since these may reduce the effect of odevixibat

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

Increased levels in liver function tests can occur in some patients receiving Bylvay. 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.

Children

Bylvay is not recommended for babies under 6 months because it is not known if the medicine is safe and effective in this age group.

Other medicines and Bylvay

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Treatment with odevixibat 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 is recommended since the uptake of lipophilic oral contraceptives may be affected by odevixibat.

It is not known if odevixibat 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 and Bylvay 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 take Bylvay

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

ALGS
- 120 micrograms odevixibat per kilogram body weight once daily (up to a maximum daily dose of 7200 micrograms once daily).
- Your doctor might recommend the dose to be reduced to 40 micrgrams of odevixibat per kilogram body weight once daily if you have diarrhoea that lasts ≥ 3 days, is considered severe, or requires IV hydration.
- If the medicine does not improve your condition after 6 months of continuous daily treatment, your doctor will recommend an alternative treatment.

No dose differences are recommended for adults.

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 or in an age-appropriate liquid (e.g. breast milk, infant formula or water).

The larger 200 and 600 micrograms capsules are intended to be opened and sprinkled on food or in an age-appropriate liquid 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 or in an age-appropriate liquid.

Detailed instructions on how to open capsules and sprinkle on food or in a liquid can be found at the end of this package leaflet.

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

If you take more Bylvay than you should

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

Possible overdose symptoms are diarrhoea, stomach and bowel problems.

If you forget to take Bylvay

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

ALGS
Take the forgotten dose as soon as possible, but do not take more than one dose per day.

If you stop taking Bylvay

Do not stop taking Bylvay without first discussing with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Side effects may occur with the following frequency:

PFIC
common (may affect up to 1 in 10 people)
- diarrhoea, including diarrhoea with bloody stool, soft stools
- abdominal (belly) pain
- enlarged liver

ALGS
Very common (may affect more than 1 in 10 people)
- diarrhoea
- abdominal (belly) pain

Common (may affect up to 1 in 10 people)
- vomiting
- enlarged liver

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bylvay

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package to protect from light. Do not store above 25 °C.

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. Contents of the pack and other information

What Bylvay contains

- The active substance is odevixibat.
  Each Bylvay 200 micrograms hard capsule contains 200 micrograms odevixibat (as sesquihydrate).
  Each Bylvay 400 micrograms hard capsule contains 400 micrograms odevixibat (as sesquihydrate).
  Each Bylvay 600 micrograms hard capsule contains 600 micrograms odevixibat (as sesquihydrate).
  Each Bylvay 1 200 micrograms hard capsule contains 1 200 micrograms odevixibat (as sesquihydrate).

- Other ingredients are:

  Capsule content

  Microcrystalline cellulose
  Hypromellose

Capsule shell

Bylvay 200 micrograms and 600 micrograms hard capsules
Hypromellose
Titanium dioxide (E171)
Yellow iron oxide (E172)

Bylvay 400 micrograms and 1 200 micrograms hard capsules
Hypromellose
Titanium dioxide (E171)
Yellow iron oxide (E172)
Red iron oxide (E172)

Printing ink

Shellac
Propylene glycol
Black iron oxide (E172)

What Bylvay looks like and contents of the pack

Bylvay 200 micrograms hard capsules:
Size 0 capsules (21.7 mm × 7.64 mm) with ivory opaque cap and white opaque body; imprinted "A200" with black ink.

Bylvay 400 micrograms hard capsules:
Size 3 capsules (15.9 mm × 5.82 mm) with orange opaque cap and white opaque body; imprinted "A400" with black ink.

Bylvay 600 micrograms hard capsules:
Size 0 capsules (21.7 mm × 7.64 mm) with ivory opaque cap and body; imprinted "A600" with black ink.

Bylvay 1 200 micrograms hard capsules:
Size 3 capsules (15.9 mm × 5.82 mm) with orange opaque cap and body; imprinted "A1200" with black ink.

Bylvay hard capsules are packed in a plastic bottle with a tamper evident, child resistant polypropylene closure. Pack size: 30 hard capsules.
Not all strengths and pack size are marketed.

Marketing Authorisation Holder & manufacturer
Ipsen Pharma
70 rue Balard
75015 Paris
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom
Ipsen Limited
Tel: +44 (0) 1753 627777

This leaflet was last revised in March 2026

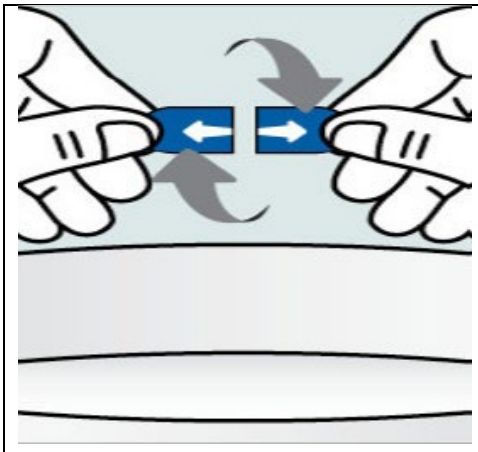
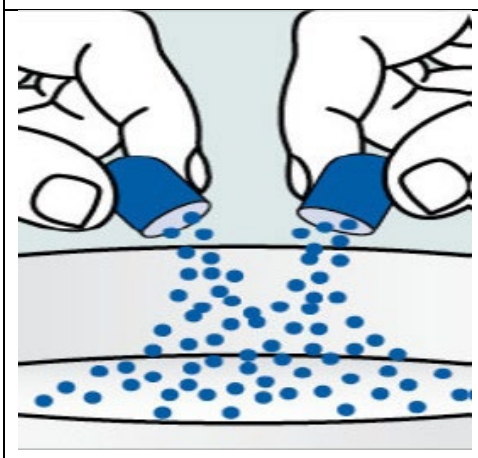
Other sources of information

Is this leaflet hard to see or read? Please phone +44 (0) 1753 627777 and ask for help.

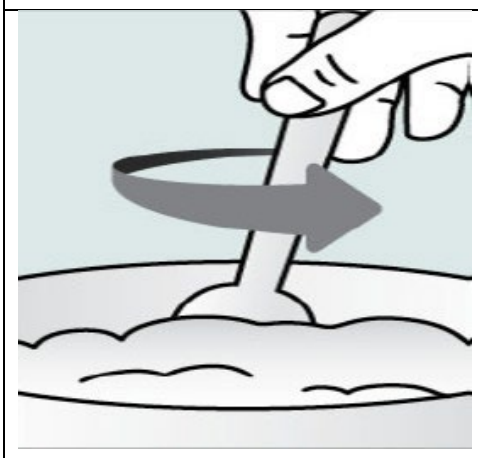
Instructions

Instructions to open capsules and sprinkle the contents on food:

Step 1. 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.

<table>
<tr><td>  </td><td>Step 2:
• Hold the capsule horizontally at both ends, twist in opposite directions.</td></tr>
<tr><td>  </td><td>Step 3:
• 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.</td></tr>
<tr><td>  </td><td>Step 4:
• Gently mix the contents of the capsule into the soft food.</td></tr>
<tr><td colspan="2">• 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</td></tr>
</table>

Instructions to open capsules and sprinkle the contents in an age appropriate liquid:

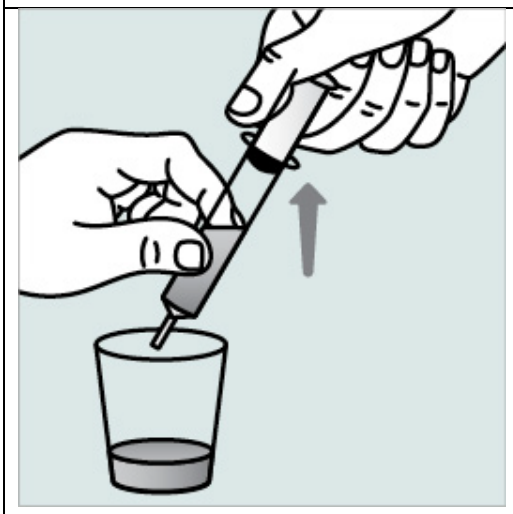
Do not administer via a bottle or “sippy cup” because the pellets will not pass through the opening. Pellets will not dissolve in liquids.

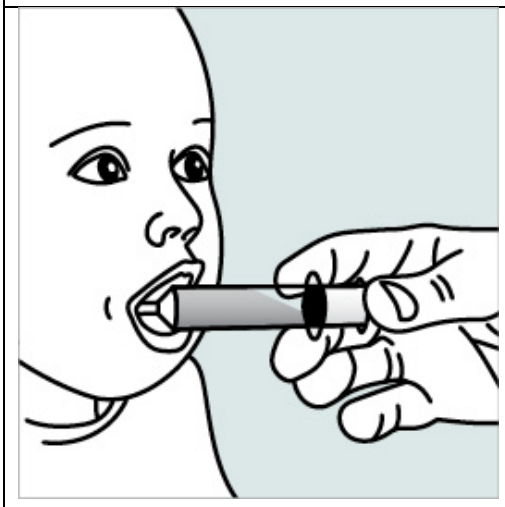
Contact your pharmacy if you do not have a suitable oral syringe for administration at home.

<table>
<tr><td> </td><td>Step 1:
• Hold the capsule horizontally at both ends, twist in opposite directions.

• Pull apart and empty the contents into a small cup or glass. Gently tap the capsule to ensure that all pellets come out. Repeat this if the dose requires more than one capsule.

• Add 1 teaspoon (5 ml) of an age appropriate liquid (breast milk, infant formula or water).

• Let the pellets sit in the liquid for approximately 5 minutes to allow complete wetting (pellets will not dissolve).</td></tr>
<tr><td>  </td><td>Step 2:
• After 5 minutes, place the tip of the oral syringe completely into the mixing cup.

• Pull the plunger of the syringe up slowly to withdraw liquid/pellet mixture into the syringe. Gently push the plunger down again to expel the liquid/pellet mixture into the mixing cup. Do this 2 to 3 times to ensure complete mixing of the pellets into the liquid.</td></tr>
<tr><td></td><td>Step 3:
• Withdraw the entire contents into the oral syringe by pulling the plunger on the end of the syringe.</td></tr>
<tr><td>  </td><td>Step 4:
• Place the tip of the oral syringe into the front of the child’s mouth between the tongue and the side of the mouth, and then gently push the plunger down to squirt the liquid/pellet mixture between your child's tongue the side of the mouth. Do not squirt liquid/pellet mixture in the back of the child's throat because this could cause gagging or choking.

• If any pellet/liquid mixture remains in the mixing cu repeat Step 3 and Step 4 until the entire dose has been administered.</td></tr>
<tr><td colspan="2">• Give the entire dose immediately after mixing. Do not store the liquid/pellet mixture for future use.</td></tr>
</table>

- Give breast milk, infant formula or other age-appropriate liquid to drink following the dose.
- Dispose of the empty capsule shells.