

BYLVAY[®] Hard Capsules

Odevixibat (200mcg, 400mcg, 600mcg, 1200mcg)

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What BYLVAY[®] is used for

BYLVAY[®] contains the active substance odevixibat.

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.
- itching caused by bile build-up in patients aged 6 months or older who have Alagille syndrome (ALGS). ALGS is a rare genetic disorder that may affect many different parts of the body, including the liver, heart, eyes, face, skeleton, blood vessels and kidneys. Patients with this syndrome have reduced bile flow, leading to a build-up of bile acids in the blood and in the liver (cholestasis) that gets worse over time and is often accompanied with severe itching.

How BYLVAY[®] works

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.

Before you use BYLVAY[®]

• When you must not use it
if you are allergic to odevixibat or any of the other ingredients of this medicine (listed under Ingredients).

• Before you start to use it

Talk to your doctor or pharmacist BEFORE taking this medicine if you have:

- been diagnosed with a complete absence or lack of function of bile sale 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 or ALGS since these may reduce the effect of odevixibat

Tell 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 enzymes might be seen in liver function tests when taking BYLVAY[®]. Before you start taking BYLVAY[®], your doctor will measure your liver function to check how well your liver is working. Your doctor will do regular checks to monitor your liver function. Your doctor may recommend more frequent monitoring if you have elevated liver function test results. Before and during treatment, your doctor may check your blood levels of vitamin A, D and E and your INR (international normalised ratio, which measures your risk of bleeding).

Children

For the treatment of PFIC, 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.

For the treatment of ALGS, 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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking BYLVAY[®].

BYLVAY[®] is not recommended during pregnancy and in women of childbearing potential not using contraception.

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 breastfeeding or avoid BYLVAY[®] treatment, considering the benefit of breastfeeding to the baby and BYLVAY[®] to the mother.

• Taking other medicines

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.

How to use BYLVAY[®]

• How much to use

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 for PFIC 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 7200 micrograms once daily).

The recommended dose for ALGS is:

- 120 micrograms odevixibat per kilogram body weight once daily (up

to a maximum of 7200 micrograms once daily).

- Your doctor may recommend the dose to be reduced to 40 micrograms odeixibat per kilogram body weight once daily if you have diarrhoea that lasts ≥ 3 days, is considered severe, or requires IV hydration.

No dose differences are recommended for adults.

• When to use it

BYLVAY® should be taken 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 and 1200 micrograms capsules are intended to be swallowed whole but may be opened and sprinkled on food or in an age-appropriate liquid.

• How long to use it

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

• If you forget to use it

If you miss taking BYLVAY®, take the forgotten dose as soon as possible, but do not take more than one dose per day.

• If you stop using it

Do not stop taking BYLVAY® without first discussing with your doctor. If you have any further questions on the use of BYLVAY®, ask your doctor or pharmacist.

• If you use too much (overdose)

Tell your doctor if you think you have taken too much BYLVAY®. Possible overdose symptoms are diarrhoea, stomach and bowel problems.

While you are using it

• Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking BYLVAY®.

Tell your doctor immediately if you become pregnant while taking this medication.

• Things you must not do

Not applicable

• Things to be careful of

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you notice any of the following side effects –

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

- Diarrhoea, including diarrhoea with bloody stool, soft stools
- Vomiting
- Abdominal (belly) pain

Common side effects in PFIC patients (may affect up to 1 in 10 people)

- Enlarged liver

Very common side effects in ALGS patients (may affect more than 1 in 10 people)

- Diarrhoea
- Abdominal (belly) pain

Common side effects in ALGS patients (may affect up to 1 in 10 people)

- Vomiting
- Enlarged liver

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of BYLVAY®

Storage

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 30°C.

- Disposal

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.

Product Description

- What it looks like

- Bylvay® 200 micrograms hard capsules are capsules with ivory opaque cap and white opaque body, imprinted “A200” with black ink.
- Bylvay® 400 micrograms hard capsules are capsules with orange opaque cap and white opaque body, imprinted “A400” with black ink.
- Bylvay® 600 micrograms hard capsules are capsules with ivory opaque cap and body, imprinted “A600” with black ink.
- Bylvay® 1200 micrograms hard capsules are capsules with orange opaque cap and body, imprinted “A1200” with black ink.

Bylvay® is available in packs containing one plastic bottle with 30 hard capsules.

- Ingredients

Active ingredient(s)

The active substance is odeixibat.

BYLVAY® 200 micrograms hard capsules: Each capsule contains 200 micrograms odeixibat (as sesquihydrate).

BYLVAY® 400 micrograms hard capsules: Each capsule contains 400 micrograms odeixibat (as sesquihydrate).

BYLVAY® 600 micrograms hard capsules: Each capsule contains 600

micrograms odevixibat (as **Serial Number**
sesquihydrate). NPRA (R1) 25/009

BYLVAY® 1200 micrograms hard
capsules: Each capsule contains 1200
micrograms odevixibat (as
sesquihydrate).

Inactive ingredients

Capsule contents: microcrystalline
cellulose, hypromellose

Capsule shell:

BYLVAY® 200 micrograms and
BYLVAY® 600 micrograms hard
capsules: hypromellose, titanium dioxide
(E171), yellow iron oxide (E172)

BYLVAY® 400 micrograms and
BYLVAY® 1200 micrograms hard
capsules:
hypromellose, titanium dioxide (E171),
yellow iron oxide (E172), red iron oxide
(E172)

Printing ink: shellac, propylene glycol,
black iron oxide (E172)

- *MAL number(s):*

BYLVAY® 200 micrograms hard
capsules

MALXXXXXXXXXX

BYLVAY® 400 micrograms hard
capsules

MALXXXXXXXXXX

BYLVAY® 600 micrograms hard
capsules

MALXXXXXXXXXX

BYLVAY® 1200 micrograms hard
capsules

MALXXXXXXXXXX

Manufacturer

Patheon France
40 Boulevard De Champaret
Bourgoin-Jallieu, 38300
France

Product Registration Holder

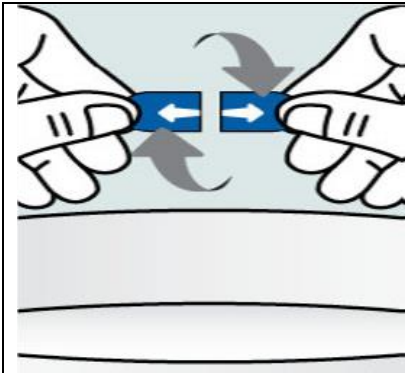
Zuellig Pharma Sdn Bhd
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Date of revision

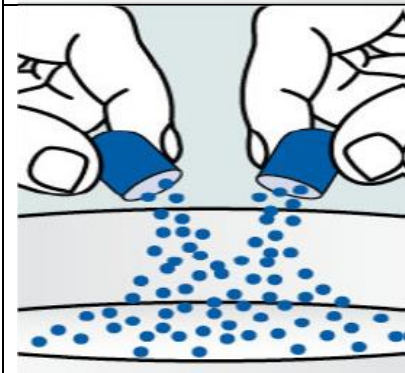
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Instructions to open capsules and sprinkle the contents on food:

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.



Step 2:
• Hold the capsule horizontally at both ends, twist in opposite directions.



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.


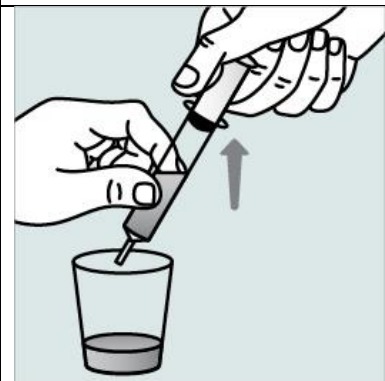
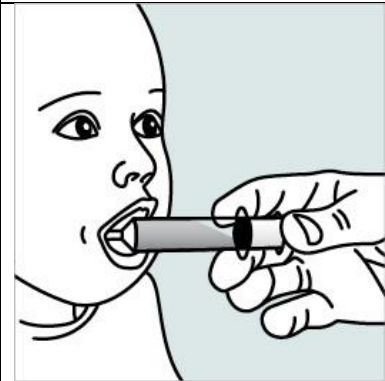


Step 4:
• Gently mix the contents of the capsule into the soft food.

- 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.

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.

		<p>Step 1:</p> <ul style="list-style-type: none"> • 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 (e.g. 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).
		<p>Step 2:</p> <ul style="list-style-type: none"> • 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 the liquid/pellet mixture into the syringe. Gently push the plunger down again to expel the liquid/pellet mixture back into the mixing cup. Do this 2 to 3 times to ensure complete mixing of the pellets into the liquid.
		<p>Step 3:</p> <ul style="list-style-type: none"> • Withdraw the entire contents into the oral syringe by pulling the plunger on the end of the syringe.
		<p>Step 4:</p> <ul style="list-style-type: none"> • 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 and 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.
<ul style="list-style-type: none"> • If any pellet/liquid mixture remains in the mixing cup, repeat Step 3 and Step 4 until the entire dose has been administered. • Give the entire dose immediately after mixing. Do not store the liquid/pellet mixture for future use. • Give breast milk, infant formula or other age-appropriate liquid to drink following the dose. • Dispose of the empty capsule shells. 		