

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking BYLVAY?

BYLVAY contains the active ingredient odeixibat. BYLVAY is used to treat progressive familial intrahepatic cholestasis (PFIC) or to treat itching caused by Alagille syndrome (ALGS) 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. ALGS is a genetic disease that can lead to a build-up of bile acids in the blood and liver that gets worse over time and is often accompanied with severe itching.

For more information, see Section [1. Why am I using BYLVAY?](#) in the full CMI.

2. What should I know before I take BYLVAY?

Do not use if you or your child have ever had an allergic reaction to BYLVAY or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child:

- have any other medical conditions or you are taking any medicines for any other condition.
- are pregnant or plan to become pregnant or are breastfeeding.
- have been diagnosed with a complete absence or lack of function of bile salt export pump protein.
- have severely reduced liver function.
- 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 odeixibat.

For more information, see Section [2. What should I know before I use BYLVAY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BYLVAY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take BYLVAY?

- The dose of BYLVAY is based on your/ your child's weight. Your doctor will work out the right number and strength of capsules to take.
- Depending on the dose used, the capsules may be swallowed whole or opened and sprinkled on soft food or in a liquid.

More instructions can be found in Section [4. How do I use BYLVAY?](#) in the full CMI.

5. What should I know while taking BYLVAY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you or your child are taking BYLVAY.• Should you experience diarrhoea while taking BYLVAY, make sure to drink enough fluids, such as water or juice, to avoid becoming dehydrated.• Make sure to keep all of your doctor's appointments so that they can monitor your condition.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking BYLVAY or lower the dosage without first discussing with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using BYLVAY?](#) in the full CMI.

6. Are there any side effects?

Common side effects of BYLVAY are: diarrhoea, including diarrhoea with bloody stool, soft stools, abdominal (belly) pain, and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BYLVAY®

Active ingredient: *odevixibat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BYLVAY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BYLVAY.**

Where to find information in this leaflet:

1. [Why am I using BYLVAY?](#)
2. [What should I know before I use BYLVAY?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use BYLVAY?](#)
5. [What should I know while using BYLVAY?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking BYLVAY?

BYLVAY contains the active ingredient *odevixibat*. BYLVAY is a medicine which increases the removal of substances called bile acids from the body. Bile acids are found in the digestive fluid called bile, which is produced by the liver and released into the gut. *Odevixibat* blocks the mechanism that returns bile acids to the blood after they have done their job in the gut. 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.**
- **alagille syndrome (ALGS) in patients aged 6 months or older. ALGS is a genetic disease that can lead to a build-up of bile acids in the blood and liver that gets worse over time and is often accompanied with severe itching.**

2. What should I know before I take BYLVAY?

Warnings

Do not use BYLVAY if:

- you are allergic to *odevixibat*, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you/your child:

- have any other medical conditions.
- take any medicines for any other condition.

- have been diagnosed with a complete absence or lack of function of bile salt export pump protein.
- have severely reduced liver function.
- 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 *odevixibat*.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Use in infants

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

Check with your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant, or intend to become pregnant.

BYLVAY is not recommended during pregnancy. Use of a barrier contraceptive method is recommended since 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.

Diarrhoea

Talk to your doctor if you develop diarrhoea while taking BYLVAY. Drink enough water, or other fluids, to prevent dehydration while you have diarrhoea.

Liver function tests

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 or your child have elevated liver function test results.

Blood tests

Your doctor may recommend assessment of Vitamin A, D and E blood levels as BYLVAY may impact the absorption of fat-soluble vitamins.

Your doctor may also monitor the blood clotting value, called INR, prior to and during BYLVAY treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with BYLVAY and affect how it works.

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

Check with your/your child's doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BYLVAY.

4. How do I take BYLVAY?

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

How much to take

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 weight. Your/your child's doctor will work out the right number and strength of capsules for you to take.

The recommended dose is:

- **For 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).
- **For ALGS:** 120 micrograms per kilogram body weight once daily.

Follow the instructions provided and use BYLVAY until your doctor tells you to stop.

If the medicine does not improve your/your child's condition after 6 months of continuous daily treatment, your doctor may recommend an alternative treatment.

When to take BYLVAY

- BYLVAY capsules should be taken once daily in the morning with or without food.

How to take BYLVAY

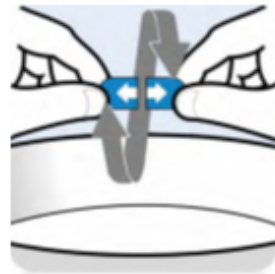
All capsules can be either swallowed whole with a glass of water or opened and sprinkled on food.

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

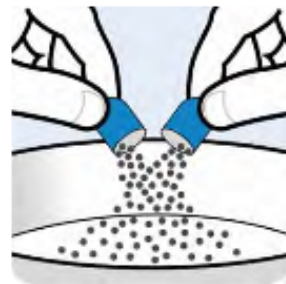
The smaller 400 micrograms and 1200 micrograms capsules are intended to be swallowed whole but may be opened and sprinkled on soft food or in a liquid.

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.

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

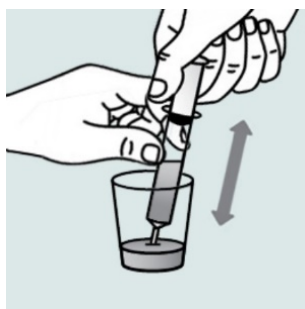
Do not give the medicine in liquid using a bottle or sippy cup. You must use an oral syringe. Ask your pharmacist for a suitable oral syringe to use at home.

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

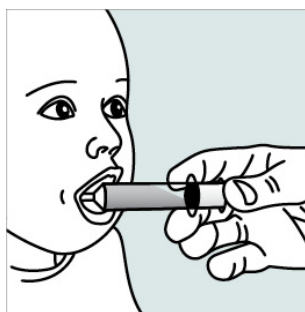
- Pull apart and empty the contents into a small cup or glass. Pellets will not pass through the opening of bottles or "sippy cups".
- Gently tap the capsule to ensure that all pellets come out. Repeat this if the dose requires more than one capsule.



- 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 in liquids).
- 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.



- Withdraw the entire contents into the oral syringe by pulling the plunger on the end of the syringe.
- 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.



- If any visible pellets or liquid mixture remain in the mixing cup or syringe, add an additional 1 teaspoon (5 mL) of age-appropriate liquid to the mixing cup and

repeat the previous three steps to mix the liquid and pellets, withdraw the entire contents, and give the dose to the child until the entire dose has been given.

- 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.

If you forget to take BYLVAY

BYLVAY should be taken regularly at the same time each morning.

If it is almost time for your/your child's next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take/give a double dose to make up for the dose you missed.

If you or your child take too much BYLVAY

If you think that you/your child may have taken too much BYLVAY, you/they may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital, taking this leaflet with you.

You should do this even if there are no signs of discomfort or poisoning.

You/your child may experience some of the following symptoms: diarrhoea, stomach and bowel problems.

5. What should I know while taking BYLVAY?

Things you should do

- Should you/your child experience episodes of diarrhoea while taking BYLVAY, make sure to drink enough fluids, such as water or juice, to avoid becoming dehydrated.
- Make sure to keep all of your doctor's appointments so that they can monitor your/your child's condition.

Remind any doctor, dentist or pharmacist you visit that you/your child are using BYLVAY.

Things you should not do

- Do not stop taking BYLVAY or lower the dosage without first discussing with your doctor.
- Do not take BYLVAY to treat any other complaints.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BYLVAY affects you.

BYLVAY is not known to have an influence on the ability to drive or capacity to use machinery.

Looking after your medicine

- Keep the medicine in the original container.
- If you take it out of its original container it may not keep well.
- Store the capsules in a cool, dry place where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you/your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your/your child's doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>stomach and intestines related:</p> <ul style="list-style-type: none">• diarrhoea, including diarrhoea with bloody stool, soft stools• vomiting• abdominal (belly) pain <p>liver related:</p> <ul style="list-style-type: none">• enlarged liver <p>blood test related:</p> <ul style="list-style-type: none">• lack of vitamin D and E• increase in the level of bilirubin in the blood (which may result in jaundice/yellow skin or eyes)• changes in blood tests used to monitor general health and function of your organs (including the liver)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Tell your/your child's doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BYLVAY contains

Active ingredient (main ingredient)	odevixibat (as sesquihydrate)
Other ingredients (inactive ingredients)	Capsule content: hypromellose, microcrystalline cellulose Capsule shell: titanium dioxide, iron oxide yellow, iron oxide red (400 and 1200 micrograms strengths only) Printing ink: shellac, propylene glycol, strong ammonia solution, isopropyl alcohol, butan-1-ol, iron oxide black

Do not take this medicine if you are allergic to any of these ingredients.

What BYLVAY looks like

BYLVAY capsules are opaque, hard gelatin capsules containing white to off-white pellets. The different strengths of BYLVAY capsules can be identified as follows (the Australian registration number 'AUST R' is also provided):

BYLVAY 200 micrograms hard capsules are size 0 capsules with an opaque white body and an opaque ivory cap with "A200" printed in black ink on the cap. (AUST R 419590)

BYLVAY 400 micrograms hard capsules are size 3 capsules with an opaque white body and a medium orange opaque cap with "A400" printed in black ink on the cap. (AUST R 419591)

BYLVAY 600 micrograms hard capsules are size 0 capsules with an opaque ivory body and cap with "A600" printed in black ink on the cap. (AUST R 419593)

BYLVAY 1200 micrograms hard capsules are size 3 capsules with a medium orange opaque body and cap with "A1200" printed in black ink on the cap. (AUST R 419592)

Australian sponsor of BYLVAY

Ipsen Pty Ltd
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