

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 using IQIRVO?

IQIRVO contains the active ingredient elafibranor. IQIRVO is used to treat adult patients with a type of liver disease known as primary biliary cholangitis (PBC).

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

2. What should I know before I use IQIRVO?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IQIRVO.

4. How do I use IQIRVO?

- Take one tablet, once a day, at about the same time each day.
- Swallow the tablet whole with water.

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

5. What should I know while using IQIRVO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using IQIRVO.• Tell your doctor immediately if you become pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.

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

6. Are there any side effects?

Abdominal pain, diarrhoea, nausea, vomiting, headache, constipation, gallstones (which may cause abdominal pain, nausea, or vomiting), muscle pain, changes to the level of an enzyme called creatine phosphokinase which may be seen in a blood test.

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.

IQIRVO[®] (EYE-KER-VO)

Active ingredient(s): *elafibranor*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IQIRVO. **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 IQIRVO.**

Where to find information in this leaflet:

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

1. Why am I using IQIRVO?

IQIRVO contains the active ingredient elafibranor, known as a dual peroxisome proliferator-activated receptor alpha/delta (PPAR α / δ) agonist that targets the liver.

IQIRVO is used to treat adult patients with a type of liver disease known as primary biliary cholangitis (PBC).

It helps to improve how your liver works by reducing the amount of bile acids produced by the liver and reducing the build-up of bile. It also acts by reducing inflammation of the liver.

IQIRVO may be given by itself or together with ursodeoxycholic acid (UDCA). Your doctor will tell you how to take this medicine.

2. What should I know before I use IQIRVO?

Warnings

Do not use IQIRVO if:

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Check with your doctor if you:

- have any other medical conditions (particularly if you have severely reduced liver function).
- take any medicines for any other condition, including cholesterol-lowering treatment ("statins").
- experience unexplained muscle pain, soreness or weakness whilst taking IQIRVO.
- experience symptoms of liver dysfunction which can include yellowing of the skin and eyes (jaundice), belly (abdominal) pain, feeling sick, vomiting, tiredness, loss of appetite and dark urine. You may need to go to hospital.

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Contact your doctor immediately if you become pregnant whilst taking IQIRVO due to possible side effects on the unborn child.

If you are a woman of childbearing potential, you should use contraception whilst taking this medicine and for 3 weeks after stopping treatment to avoid any harm to the unborn child. Your doctor will advise you on the best contraception for you.

Your doctor may ask you to take a pregnancy test before starting treatment with IQIRVO to ensure you are not pregnant prior to starting treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed whilst taking this medicine as it is unknown if IQIRVO will pass to your child in your milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IQIRVO.

4. How do I use IQIRVO?

How much to take

- The recommended dose is one tablet, once a day, at about the same time each day.
- You can take IQIRVO with or without food.
- Swallow the tablet whole with water.
- Do not crush the tablet.
- Follow the instructions provided and use IQIRVO until your doctor tells you to stop.

When to take IQIRVO

- IQIRVO should be taken at about the same time each day.

If you forget to take IQIRVO

IQIRVO should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose when it is due, skipping the missed dose.

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

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

If you take too much IQIRVO

If you think that you have taken too much IQIRVO, you 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.

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

5. What should I know while using IQIRVO?

Things you should do

Call your doctor straight away if you:

- experience unexplained muscle pain, soreness or weakness whilst taking IQIRVO.
- experience any of the symptoms under Serious Side Effects in Section 6.

Remind any doctor, dentist or pharmacist you visit that you are using IQIRVO.

Things you should not do

- Do not stop using this medicine suddenly.

Monitoring

- Your doctor may carry out blood tests and tell you to stop IQIRVO temporarily or permanently if there are changes to either your liver function tests or the level of an enzyme in your blood called creatine phosphokinase.

Looking after your medicine

- Store below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly.

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 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 doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Signs of gallstones: <ul style="list-style-type: none">• Abdominal (stomach area) pain• Nausea• Vomiting• Yellowing of the skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Less serious side effects

Less serious side effects	What to do
<p>Nervous system related:</p> <ul style="list-style-type: none">• Headache <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Abdominal pain• Diarrhoea• Constipation• Nausea (feeling sick)• Vomiting (being sick) <p>Skin related:</p> <ul style="list-style-type: none">• Itchy rash <p>Muscle or bone related:</p> <ul style="list-style-type: none">• Muscle pain <p>Blood test related:</p> <ul style="list-style-type: none">• Changes to the level of an enzyme called creatine phosphokinase which may be seen in a blood test• Changes to the level of a substance in the blood called creatinine which may be seen in a blood test	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

	macrogol 3350 purified talc iron oxide yellow iron oxide red
Potential allergens	n/a

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

What IQIRVO looks like

IQIRVO 80 mg film-coated tablets are round, orange, and debossed with 'ELA 80' on one side. Available in bottles of 30 tablets (AUST R 441770).

Australian Sponsor of IQIRVO

Ipsen Pty Ltd
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IQIRVO® is a registered trademark of GENFIT.

This leaflet was prepared in March 2025.

Tell your 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 IQIRVO contains

Active ingredient (main ingredient)	elafibranor
Other ingredients (inactive ingredients)	microcrystalline cellulose povidone croscarmellose sodium magnesium stearate colloidal anhydrous silica polyvinyl alcohol titanium dioxide