The IQIRVO EFFECT

Transforming your PBC treatment journey

What is IQIRVO® used for?

IQIRVO is a prescription medicine used to treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well to UDCA, or used alone in patients unable to tolerate UDCA.

IQIRVO is not recommended for use in people who have symptoms or signs of advanced liver disease. It is not known if taking IQIRVO will improve your chance of survival or prevent liver decompensation.

It is not known if IQIRVO is safe and effective in children under 18 years of age.

What Warnings should I know about IQIRVO?

- IQIRVO can cause **muscle problems (myalgia, myopathy, rhabdomyolysis) and muscle pain** that can be severe. Treatment with IQIRVO may cause muscle pain or worsen existing pain and can increase the level of an enzyme in your blood called creatine phosphokinase (CPK); both can be a sign of muscle damage. If there is new or worsening muscle pain, your healthcare provider may examine you and perform a blood test. Stop taking IQIRVO and call your healthcare provider right away if you have any of the following signs or symptoms: severe muscle pain, unexplained soreness, unexplained muscle weakness, or dark, reddish urine.

Please see additional Important Safety Information throughout and full Prescribing Information.

IQIRVO®
elafibranor 80 mg tablets

Keeping your primary biliary cholangitis (PBC) in check

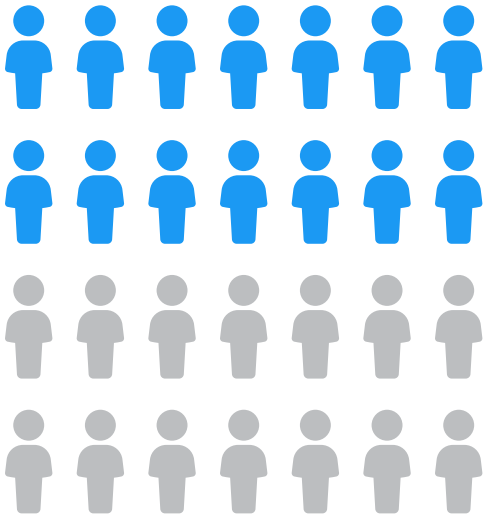
Be proactive—staying ahead of rising alkaline phosphatase (ALP) numbers may help slow disease progression, leading to better outcomes.

In PBC, **liver inflammation and buildup of toxins** can lead to liver damage and reduced liver function.

PBC is progressive, meaning it can get worse over time. **Slowing progression early can result in better outcomes**.

You can **decrease your likelihood of disease progression** with treatment that lowers ALP and maintains bilirubin within normal range.

Could you achieve more with your PBC treatment?



UP TO

50%

OF PEOPLE

do not respond well enough to ursodiol[a] and **may require additional treatment.**

[a]Ursodeoxycholic acid, or **ursodiol**, may also be referred to as UDCA.

If you aren't responding well enough to your current treatment, it may be time to reevaluate your treatment approach.

This is IQIRVO®—a different approach to PBC treatment

IQIRVO is thought to act on multiple targets in the liver. Two of these targets are PPAR alpha and PPAR delta.[a]

In the liver, PPAR alpha and PPAR delta help control:

liver inflammation **&** levels of certain substances, like bile acids

[a]This information is based on animal studies, and the way IQIRVO works is not fully understood.

PPAR=peroxisome proliferator-activated receptor.

If you need more from your PBC treatment, adding IQIRVO can help.

IQIRVO was studied in a 52-week clinical trial of 161 people with PBC.

- 102 people took IQIRVO in addition to ursodiol, and 6 people who were intolerant to ursodiol took IQIRVO alone
- The results were compared with 53 people who took ursodiol alone

13x MORE PEOPLE WITH PBC

met the established treatment goals when taking IQIRVO compared to people who took ursodiol alone.[b]

Treatment goals in the trial were defined as:

Lowering ALP to less than 1.67 times the upper limit of normal (ULN)[c]

Decreasing ALP by at least 15%

Maintaining normal bilirubin

[b]51% of people taking IQIRVO met the treatment goals compared to 4% of people who took ursodiol alone.

After the trial was over, **97% of people taking IQIRVO** chose to continue taking IQIRVO in an ongoing follow-up study.

[c]The upper limit of normal, or ULN, is the high end of a normal range for a lab value. When assessing a person's response to treatment for PBC, the definition of response may include an ALP level in relation to the ULN (for example, an ALP level of 1.67 x ULN).

What Warnings should I know about IQIRVO? (continued)

- IQIRVO may increase the risk of **bone fractures**. Tell your healthcare provider about any bone fractures, or if you develop pain, or have changes in your ability to move around.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Achieve more response from your PBC treatment

In the clinical trial:

ALP lowered

IQIRVO® **lowered ALP** in as quickly as 4 weeks, and the effects were **sustained** over 52 weeks.

ALP normalized

By 52 weeks, some people taking IQIRVO (15%) achieved a **normal ALP level**, compared to no one who took ursodiol alone.

IQIRVO can lower and even normalize ALP.

Itch-related results

IQIRVO was studied in people who had moderate-to-severe levels of itch defined as a PBC Worst Itch Numeric Rating Scale (WI-NRS) score greater than or equal to 4.

People taking IQIRVO reported an average reduction of 1.93 points in the WI-NRS score, compared to people taking ursodiol alone (average reduction of 1.15 points).

When asked questions from the itch section of the PBC-40 questionnaire and the 5-D itch scale:

People taking IQIRVO reported an average reduction of 2.5 points in the PBC-40 itch score, compared to people taking ursodiol alone (average reduction of 0.1 points).

&

People taking IQIRVO reported an average reduction of 4.2 points in the 5-D itch total score, compared to people taking ursodiol alone (average reduction of 1.2 points).

Itch was a secondary outcome of the study and results did not reach statistical significance. Data should be reviewed with caution. If you have questions about this limitation, your doctor can help explain it further.

What Warnings should I know about IQIRVO? (continued)

- IQIRVO may cause **harm to an unborn baby when taken during pregnancy**. Women taking IQIRVO who can become pregnant should use effective birth control during treatment and for 3 weeks after the last dose of IQIRVO. Talk to your healthcare provider about birth control methods that may be right for you. Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Safety and tolerability

The most common side effects in people who took IQIRVO were:

- Weight gain (23%)
- Diarrhea (11%)
- Abdominal pain (11%)
- Nausea (11%)
- Vomiting (11%)
- Arthralgia (8%)
- Constipation (8%)
- Muscle pain (7%)
- Fracture (6%)
- Gastroesophageal reflux disease (6%)
- Dry mouth (5%)
- Weight loss (5%)
- Rash (5%)

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Once-daily dosing

IQIRVO is an 80-mg pill taken orally.
IQIRVO can be taken with or without food.

Please see additional Important Safety Information throughout and full Prescribing Information.

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IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

Dedicated support for patients and families

IPSEN CARES® patient support program can help you get access to your IQIRVO® (elafibranor) prescription with the information and support you need.

Your IPSEN CARES Team

Patient Access Managers (PAM) are knowledgeable about health insurance and can help you understand what is needed to get access to, and afford, IQIRVO.

Your PAM can:

- Provide information and support to help you prepare to talk to your healthcare provider, specialty pharmacy, and insurance company
- Work with you to understand your specific situation and healthcare coverage needs
- Help to identify possible financial support programs for which you may qualify

Patient Education Liaisons (PEL) are healthcare educators and are experienced in working with individuals living with certain conditions.

Your PEL can:

- Provide educational information to help you, your family, and your caregivers better understand your condition, access needs, and prescribed treatment expectations
- Help you to understand your specific situation and healthcare needs based on the direction and advice provided by your healthcare provider
- Work in connection with your healthcare providers to support you and your caregivers through some of the many challenges of living with your condition

Personalized Support Services

Financial & Insurance Assistance

Dedicated, Individualized Support

Continuity of Care

Educational Materials & Programs

Enrolling in IPSEN CARES is quick and easy.
Your healthcare provider must complete the IPSEN CARES Enrollment Form, and you must review and sign the patient authorization section.

To learn more about IPSEN CARES:
ipsencares.com • (866) 435-5677 • Monday-Friday, 8:00 AM – 8:00 PM ET
support@ipsencares.com

Are you ready to transform your PBC experience?

Ask your doctor if IQIRVO® may be right for you.

What Warnings should I know about IQIRVO? (continued)

- IQIRVO can cause **liver problems** and abnormal liver blood test results. Your healthcare provider should do tests before starting and during treatment with IQIRVO to check your liver function. Tell your healthcare provider right away if you experience any of the following during treatment with IQIRVO: swelling of your stomach-area (abdomen), yellowing of your skin or whites of your eyes, black, tarry, or bloody stools, mental changes such as confusion, being sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality, or coughing up or vomiting blood, or your vomit looks like coffee grounds. If you have severe stomach-area (abdomen) pain, nausea, vomiting, diarrhea, loss of appetite or weight loss, new or worsening fatigue, weakness, fever and chills, light-headedness, or less frequent urination, tell your healthcare provider right away.

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What Warnings should I know about IQIRVO? (continued)

- Some people taking IQIRVO had **allergic reactions**, which may include rash, trouble breathing, itching, or swelling of your face, lips, tongue, or throat. If you experience any of these, stop taking IQIRVO, call your healthcare provider right away or go to the nearest hospital emergency room.
- IQIRVO can cause **blockage of the bile duct and may increase your risk of gallstones**. Call your healthcare provider right away if you develop pain in the upper right stomach area or yellowing of the skin.

You should not use IQIRVO if you:

- Have advanced liver disease.
- Are pregnant or plan to become pregnant. IQIRVO can harm your unborn baby. You should not become pregnant during treatment with IQIRVO.
- Are breastfeeding or plan to breastfeed. It is not known if IQIRVO passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you take IQIRVO.

What are the side effects of IQIRVO?

The most common side effects of IQIRVO include weight gain, diarrhea, stomach pain, nausea, vomiting, joint pain, constipation, muscle pain, bone fractures, gastroesophageal reflux disease (GERD), dry mouth, weight loss, and rash. These are not all of the possible side effects of IQIRVO. Call your doctor for medical advice about side effects.

What other medications might interact with IQIRVO?

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IQIRVO can affect the way certain medicines work. Certain medicines may affect the way IQIRVO works. If you take a bile acid binding resin, take IQIRVO at least 4 hours before or after you take your bile acid resin.

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

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