

# A guide to help you and your doctor decide if IQIRVO<sup>®</sup> is right for you

### **Could you achieve more with your PBC treatment?**

Bring this guide to your next appointment to help you and your doctor:



### What is IQIRVO<sup>®</sup> 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.

### Your current treatment goals

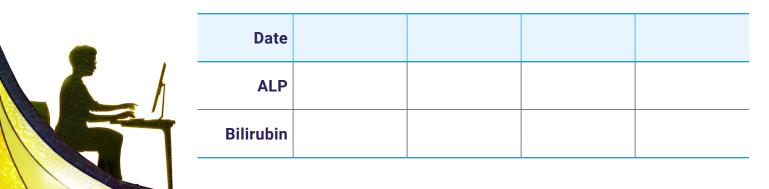
### It's important to understand the goals of your PBC treatment plan and establish how you're responding to treatment.

Answer these questions before your next appointment to help you assess your PBC treatment experience:



### Are my biochemical levels aligned with my treatment goals?

The results of your liver lab tests, including alkaline phosphatase (ALP) and bilirubin levels, are used by your doctor to assess if your current treatment is working. If these results are available to you, you can track them in the chart below. Sharing this chart with your doctor can help to identify trends and decide if it's time to rethink your treatment goals.



## **Discover IQIRVO®**

# Use these questions when talking to your doctor and see if IQIRVO is right for you:



#### How is IQIRVO pronounced?

IQIRVO is pronounced "eye-ker-vo."

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### How can adding IQIRVO help me meet my treatment goals?



Can IQIRVO increase the likelihood that I experience symptoms of PBC?

Can IQIRVO help lower the risk of my PBC progressing?



Can I take IQIRVO with my other medication(s)?

What are the most common side effects of IQIRVO?

How do I get started on IQIRVO?



For more information, visit iqirvo.com



### 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 <u>Prescribing Information</u>.



### 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.
- 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.
- 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-thecounter 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 <u>www.fda.gov/medwatch</u>. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see full Prescribing Information.



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