IPSEN CARES® PATIENT EDUCATION LIAISON (PEL) ENROLLMENT FORM

Questions? Call IPSEN CARES at (866) 435-5677

IQIRVO® elafibranor 80 mg tablets

Please fill out this form completely and then email to support@ipsencares.com

By completing this enrollment form, you may be eligible to receive individualized support provided by an IPSEN CARES PEL, including:

- **Providing information and educational materials** to help you, your family, and your caregivers better understand your condition and treatment expectations for IQIRVO
- **Helping support your specific situation and healthcare needs** in alignment with the treatment plan created by you and your doctor
- **Supporting you and your caregivers** through some of the many challenges of living with a chronic condition

An IPSEN CARES PEL will reach out after enrollment.

IPSEN CARES PELs are provided by Ipsen and do not work under the direction of your healthcare provider or give medical advice.

Note: This form is only to be used for enrollment in the IPSEN CARES PEL Support Offering.

STEP 1

PATIENT INFORMATION

Patient Name (First & Last) _____

Home Phone # _____ Mobile Phone # _____

Patient Address _____

City _____ State _____ Zip _____

Date of Birth (MM/DD/YY) ____ / ____ / ____ Email _____

If completed by a Caregiver/Legal Guardian, relationship to patient _____

Caregiver/Legal Guardian Name (First & Last) _____

Caregiver/Legal Guardian Phone # _____

Prescribing Doctor Name _____ Prescribing Doctor Phone # _____

I give permission to Ipsen to contact me by text message for the purposes described in Step 2 on Page 3. ○ Yes ○ No

If Yes, please initial here: _____

Diagnosis:

K74.3 Primary Biliary Cholangitis (PBC)

IQIRVO is indicated for the treatment of adult patients with PBC in combination with ursodeoxycholic acid (UDCA) for adults with inadequate response to UDCA or as monotherapy for adults with an intolerance to UDCA.

This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). IQIRVO is not recommended for people who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

I confirm that I have been prescribed IQIRVO for the treatment of Primary Biliary Cholangitis (PBC).

If yes, please initial here: _____

Please see Indication and Important Safety Information on page 4 and accompanying full Prescribing Information.

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Please fill out this form completely and then email to support@ipsencares.com

STEP 2

PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION: IPSEN CARES® PROGRAM

I authorize my doctor(s) and their staff (including those pharmacies that may receive my prescription for IQIRVO®) to disclose my protected health information ("PHI"), including health information about insurance, prescription, care management, and medical condition to Ipsen Biopharmaceuticals, Inc., and/or its affiliates, and/or its agents or third-party vendors that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES) program (collectively, "Ipsen") in order for Ipsen to (1) enroll me in the IPSEN CARES Patient Education Liaison Support Offering; (2) communicate with my doctors and health plans about my treatment plan; (3) provide support services, including patient education for IQIRVO; (4) help get IQIRVO shipped to me or my healthcare provider; and (5) facilitate my participation in IQIRVO patient programs as I have requested or may request.

I agree that, using the contact information I provide, Ipsen may contact me by phone, mail, and/or email for reasons related to the IPSEN CARES program and support services, including (1) determining I am eligible for assistance and related support services, (2) leaving messages for me that disclose that I am on IQIRVO therapy and/or applied for IPSEN CARES support services and am or am not eligible for assistance; (3) operating IPSEN CARES patient programs that might help me pay for or access my medicines; and (4) confirming receipt of medications. I consent to being contacted by an IPSEN CARES program representative in order for the program to obtain further information or clarification regarding any adverse event I may experience. I also give Ipsen permission to share my PHI and other information with people and companies that work with IPSEN CARES, including; government agencies, insurance providers, my doctor(s) and other people, or institutions who are involved in my healthcare, such as pharmacies and hospitals; and/or other organizations that might help me pay for my medication. All information that I provide may be used by Ipsen or any third party working on behalf of Ipsen in connection with IPSEN CARES. I understand that my healthcare providers may receive remuneration from Ipsen in connection with my PHI and/or for any therapy support services provided to me.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws, and Ipsen may re-disclose it; however, Ipsen has agreed to make reasonable efforts to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I can withdraw this authorization by contacting IPSEN CARES at (866) 435-5677 or mailing a letter requesting such revocation to IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560, but it will not change any actions taken before I withdraw this authorization. Withdrawal of this authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon this authorization.

Please see Indication and Important Safety Information on page 4 and accompanying full Prescribing Information.

Please fill out this form completely and then email to support@ipsencares.com

STEP 2 (continued)

PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION: IPSEN CARES® PROGRAM (continued)

I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in the IPSEN CARES Patient Education Liaison Support Offering, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment, or affect my insurance enrollment or eligibility for insurance coverage.

This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I understand that I will receive a copy of the signed authorization.

I confirm that any information that I provide to IPSEN CARES is complete and true.

I confirm that I am a resident of the United States (including its territories). I understand that Ipsen may revise, change, or terminate this program at any time without notice.

Patient/Legal Guardian Signature _____ **Date** _____

ADDITIONAL PRODUCT AND SUPPORT INFORMATION

Text Communications

To the extent that I have opted in under Step 1 of this form, I agree to be contacted by autodialed text messages ("texts") at the mobile phone number I have provided for the purpose of helping me stay on therapy, which may promote or advertise the Ipsen products included in the therapy plan, and/or which may include provision of educational materials and information about programs that support patients. I certify that the number I am providing belongs to me and not a family member or third party. I understand that I may opt out of individual communications or all text communications entirely at any time by calling (866) 435-5677 or replying "STOP" by text to any text from Ipsen. Ipsen will not sell or rent this information and will use it only in accordance with this authorization and consent. Consent to being contacted by text messages is not a condition of participation in the IPSEN CARES Patient Education Liaison Support Offering or the purchase of any products or services. I understand that my cellular service carrier's data and text messaging rates may apply. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

We are collecting personal information in order to fulfill your request. Please see Ipsen's privacy policy at https://www.ipsen.com/us/privacy-policy/. Residents of certain states have additional rights regarding the collection, use, and disclosure of their personal information. For more information, please see Ipsen's Supplemental State Privacy Notice at https://www.ipsen.com/us/Supplement-Website-Privacy-Notice/.

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IQIRVO® elafibranor 80 mg tablets

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.
- 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.
- 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-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.

Please see full Prescribing Information.

IPSEN CARES® Coverage, Access, Reimbursement & Education Support