Package leaflet: Information for the patient

Iqirvo **80 mg film-coated tablets**
elafibranor

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Iqirvo is and what it is used for

Iqirvo contains the active substance elafibranor known as a dual peroxisome proliferator-activated receptor alpha/delta (PPARα/δ) agonist that targets the liver.

This medicine 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 you need to know before you take Iqirvo

Do not take Iqirvo
- if you know that you are allergic to elafibranor or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Iqirvo if you have severely reduced liver function, or if you have previous history of unexplained muscle pain.

Talk to your doctor immediately if you experience unexplained muscle pain, soreness or weakness whilst taking this medicine.

Your doctor may carry out blood tests before prescribing elafibranor to you, and during the course of your treatment. Your doctor may also 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.

Children and adolescents
Do not give this medicine to children and adolescents below 18 years of age.

Other medicines and Iqirvo
Iqirvo is not known to interact with other medicines, but please tell your doctor if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor.

Pregnancy and breast-feeding
Talk to your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning on becoming pregnant.
Contact your doctor immediately if you become pregnant whilst taking Iqirvo due to the possible adverse 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 starting treatment.

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

Iqirvo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Iqirvo

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

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 tablets whole with water. Do not crush, chew or split the tablets.

If you take more Iqirvo than you should
If you have taken more of this medicine than you have been instructed to, talk to a doctor or go to the hospital taking the tablets and this leaflet with you straight away.

If you forget to take Iqirvo
If you forget to take a dose, take your next dose when it is due, skipping the missed dose.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Iqirvo
Do not stop taking this medicine unless you have discussed this with your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects are:

Very common side effects (may affect more than 1 in 10 people):
- Abdominal pain
- Diarrhoea
- Nausea (feeling sick)
- Vomiting (being sick)

Common side effects (may affect up to 1 in 10 people):
- Headache
- Constipation
- Gallstones (which may cause abdominal pain, nausea or vomiting)
- Changes to the level of an enzyme called creatine phosphokinase which may be seen in a blood test
- Muscle pain (see 'Warnings and Precautions')

Uncommon (may affect 1 in 100 people)
- Itchy rash
- Changes to the level of a substance in the blood called creatinine which may be seen in a blood test

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Iqirvo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.
After first opening, the medicine may be stored for a maximum of 30 days.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Iqirvo contains
The active substance is elafibranor.
Each film-coated tablet contains 80 mg of elafibranor.

The other ingredients are:

- **Tablet contents:** microcrystalline cellulose, povidone, croscarmellose sodium, anhydrous colloidal silica, magnesium stearate.
- **Film-coating:** polyvinyl alcohol-part hydrolysed titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172).

What Iqirvo looks like and contents of the pack

Iqirvo 80 mg film-coated tablets are orange, round, approximately 8 mm diameter, and identified with "ELA 80" on one side.

Iqirvo is available in child-resistant bottles of 30 tablets.

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This leaflet was last revised in June 2024.

Other sources of information

Is this leaflet hard to see or read? Please phone +44 (0) 1753 627 777 and ask for help.