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Iqirvo (*elafibranor*)

An overview of Iqirvo and why it is authorised in the EU

What is Iqirvo and what is it used for?

Iqirvo is used to treat adults with a liver disease known as primary biliary cholangitis.

Primary biliary cholangitis is an autoimmune condition in which there is gradual destruction of the bile ducts in the liver. These ducts transport fluid called bile from the liver to the intestines, where it is used to help digest fats. As a result of the damage to the ducts, bile builds up in the liver causing damage to liver tissue. This may lead to scarring and liver failure and may increase the risk of liver cancer.

Iqirvo is used together with another medicine, ursodeoxycholic acid (UDCA), in patients for whom UDCA alone does not work well enough, and on its own in patients who cannot take UDCA.

Primary biliary cholangitis is rare, and Iqirvo was designated an 'orphan medicine' (a medicine used in rare diseases) on 25 July 2019. Further information on the orphan designation can be found on the EMA website.

Iqirvo contains the active substance elafibranor.

How is Iqirvo used?

Iqirvo is available as tablets to be taken by mouth once a day. The medicine can only be obtained with a prescription.

For more information about using Iqirvo, see the package leaflet or contact your doctor or pharmacist.

How does Iqirvo work?

The active substance in Iqirvo, elafibranor, works by attaching to and activating cell receptors (targets) called 'PPAR receptors', which are thought to be involved in controlling the levels of bile acid and in the process of liver inflammation and scarring. By activating PPARs, Iqirvo regulates the levels of bile acid. The medicine also has an anti-inflammatory effect on the liver.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Iqirvo have been shown in studies?

Iqirvo was compared with placebo (a dummy treatment) in a main study involving 161 adults with primary biliary cholangitis. The majority of patients had been taking UDCA for at least 1 year and continued taking it during the study but some patients had stopped taking UDCA due to side effects. The measure of effectiveness was based on the number of patients whose blood levels of the substances ALP and bilirubin (markers of liver damage) decreased to a level considered normal (for both ALP and bilirubin) and by at least 15% (for ALP) after 1 year of treatment.

The study showed that Iqirvo was more effective than placebo at reducing the blood levels of ALP and bilirubin. Overall, levels decreased by the required amount in around 51% (55 out of 108) of patients treated with Iqirvo, compared with around 4% (2 out of 53) of patients on placebo.

What are the risks associated with Iqirvo?

For the full list of side effects and restrictions with Iqirvo, see the package leaflet.

The most common side effects with Iqirvo (which may affect more than 1 in 10 people) include abdominal (belly) pain, diarrhoea, nausea (feeling sick) and vomiting. In the clinical study, these side effects were mostly mild to moderate in severity, occurred early during treatment and tended to resolve within days to a few weeks.

Iqirvo must not be used in women who are pregnant, could be pregnant or in women who are able to have children when they do not use contraception.

Why is Iqirvo authorised in the EU?

Patients with primary biliary cholangitis have limited treatment options. Iqirvo has been shown to reduce the blood levels of ALP and bilirubin in patients with primary biliary cholangitis. The extent of the reductions in ALP and bilirubin is considered indicative of an improvement in the condition of the liver. However, as primary biliary cholangitis progresses very slowly, it needs to be confirmed in a further study if these findings translate into long-term clinical benefits. The safety profile of the medicine was considered to be favourable, with side effects that were tolerable and usually resolved in a short time.

The European Medicines Agency therefore decided that Iqirvo’s benefits are greater than its risks and it can be authorised for use in the EU.

Iqirvo has been given conditional authorisation. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Iqirvo. To confirm the safety and effectiveness of Iqirvo in adults with primary biliary cholangitis, the company must conduct a study to investigate the long-term clinical benefits in patients with primary biliary cholangitis treated with Iqirvo. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Iqirvo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Iqirvo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Iqirvo are continuously monitored. Suspected side effects reported with Iqirvo are carefully evaluated and any necessary action taken to protect patients.

Other information about Iqirvo

Iqirvo received a conditional marketing authorisation valid throughout the EU on 19 September 2024.

Further information on Iqirvo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/iqirvo.

This overview was last updated in 08-2024.