IQIRVO® Film-coated Tablets

Elafibranor (80mg)

What is in this leaflet

What IQIRVO® is used for

IQIRVO® contains the active substance elafibranor which acts on 2 types of receptors (PPAR alpha and PPAR delta). IQIRVO® is used in adults to treat primary biliary cholangitis (PBC), a type of liver disease in which the bile ducts are slowly destroyed, making it harder for bile to flow through. Bile is a fluid that helps digest food, especially fats. When the bile cannot flow into the digestive tract, it backs up in the liver (this is called cholestasis), where it damages liver tissues. This can decrease liver function and cause inflammation. IQIRVO® can be used together with ursodeoxycholic acid (UDCA), or by itself in patients who cannot use UDCA.

How IQIRVO® works

The active substance in IQIRVO®, elafibranor, works by activating the PPAR alpha and PPAR delta receptors. These proteins are thought to regulate levels of bile acids, inflammation, and fibrosis (formation of scar tissue). This reduces the production and the build-up of bile in the liver and also reduces inflammation of the liver.

Before you use IQIRVO®

- *When you must not use it*

- If you are allergic to elafibranor or any of the other ingredients of this medicine (listed under Ingredients)
- If you are pregnant, if you think you might be pregnant or if you do not use any method of contraception to prevent pregnancy

- *Before you start to use it*

IQIRVO® can increase blood levels of liver enzymes and bilirubin (a breakdown product of red blood cells). Your doctor may carry out blood tests to check your liver before and during treatment. If there are abnormal results from these liver tests, your doctor may temporarily stop treatment until they return to normal. Tell your doctor immediately if you develop symptoms of liver dysfunction including yellowing of the skin and eyes (jaundice), belly (abdominal) pain, feeling sick, vomiting, tiredness, loss of appetite and dark urine.

IQIRVO® may increase blood levels of creatine phosphokinase (an enzyme released into the blood when muscle is damaged). Your doctor may run blood tests to check your levels of creatine phosphokinase before and during treatment, particularly if you are taking medicines known as HMG-CoA reductase inhibitors, such as atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin. Talk to your doctor immediately if you experience unexplained muscle pain, soreness or weakness whilst taking this medicine.

Children

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

Pregnancy and breastfeeding

Do not take IQIRVO® if you are pregnant, if you think you might be pregnant or if you do not use any method of contraception to prevent pregnancy. IQIRVO® may harm the unborn child.

Your doctor may ask you to take a pregnancy test before starting treatment with IQIRVO® to ensure you are not pregnant prior to starting treatment.

If you are a woman of childbearing potential, you should use effective contraception (birth control) whilst taking this medicine and for at least 3 weeks after stopping treatment to avoid any harm to the unborn child. Your doctor will advise on the best contraception for you.

It is unknown if IQIRVO® passes into human milk. A risk to the nursing child cannot be excluded. You should not breastfeed your baby during treatment and for 3 weeks after the last dose.

- *Taking other medicines*

Tell you doctor if you are taking, have recently taken or might take any other medicines.

How to use IQIRVO®

- *How much to use*

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

The recommended dose is one 80mg tablet, once a day. Swallow the tablet whole with water. Ask your doctor before taking IQIRVO® if you have advanced cirrhosis (a type of chronic, progressive liver disease in which liver cells are replaced by scar tissue) with severely reduced liver function (Child-Pugh C).

- *When to use it*

IQIRVO® should be taken once a day.

Swallow the tablet whole with water.

- *How long to use it*

Do not stop taking IQIRVO® 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.

- *If you forget to use it*

If you forget to take IQIRVO®, skip the dose and take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

- *If you stop using it*

Do not stop taking IQIRVO® 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.

- *If you use too much (overdose)*

If you have taken more IQIRVO® than you have been instructed to, talk to a doctor or go to the hospital straight away. Take the tablets and this leaflet with you.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Not applicable

- *Things to be careful of*

IQIRVO® contains sodium

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

Side effects

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

Very common side effects (may affect more than 1 in 10 people):

- Belly (abdominal) pain
- Diarrhoea
- Feeling sick (nausea)
- Vomiting

Common side effects (may affect up to 1 in 10 people):

- Headache
- Constipation
- Gallstones (cholelithiasis) that can block the flow of bile causing abdominal pain, nausea or vomiting
- An increase in creatine phosphokinase, as measured in blood tests
- Muscle pain (myalgia)

Uncommon (may affect 1 in 100 people):

- Itchy rash (pruritic rash)
- Increase in creatinine, as measured in blood tests. Blood levels of creatinine are measured to monitor kidney function

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IQIRVO®

Storage

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 carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

- *Disposal*

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.

Product Description

- *What it looks like*

IQIRVO® 80mg film-coated tablets are orange, round, debossed with 'ELA 80' on one side.
IQIRVO® is available in child-resistant bottles of 30 film-coated tablets.

- *Ingredients*

Active ingredient(s)

The active substance is elafibranor.

Each film-coated tablet contains 80mg of elafibranor.

Inactive ingredients

Tablet contents: microcrystalline cellulose, povidone, croscarmellose sodium, anhydrous colloidal silica, magnesium stearate

Film-coating: polyvinyl alcohol-part hydrolyzed, titanium dioxide, macrogol, talc, iron oxide yellow, iron oxide red

- *MAL number(s):*

IQIRVO® 80mg Film-coated Tablet
MAL26036114ACZ

Manufacturer

Delpharm Milano S.r.l
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Product Registration Holder

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