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EPAR summary for the public

Ivabradine Accord

ivabradine

This is a summary of the European public assessment report (EPAR) for Ivabradine Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ivabradine Accord.

For practical information about using Ivabradine Accord, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ivabradine Accord and what is it used for?

Ivabradine Accord is a heart medicine used to treat the symptoms of long-term stable angina (pains to the chest, jaw and back, brought on by physical effort) in adults with coronary artery disease (heart disease caused by blockage of the blood vessels that supply the heart muscle). The medicine is used in patients with a normal heart rhythm whose heart rate is at least 70 beats per minute. It is used either in patients who cannot take beta-blockers (another type of medicine to treat angina) or in combination with a beta-blocker in patients whose disease is not controlled by beta-blockers alone.

Ivabradine Accord is also used in patients with long-term heart failure (when the heart cannot pump enough blood to the rest of the body) and a normal heart rhythm whose heart rate is at least 75 beats per minute. It is used in combination with standard therapy including beta-blockers, or in patients who cannot be treated with beta-blockers.

Ivabradine Accord contains the active substance ivabradine. It is a 'generic medicine'. This means that Ivabradine Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Procoralan. For more information on generic medicines, see the question-and-answer document here.

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How is Ivabradine Accord used?

Ivabradine Accord is available as tablets (5 and 7.5 mg) and can only be obtained with a prescription. The recommended starting dose is 5 mg twice a day with meals, which the doctor may increase to 7.5 mg twice a day or decrease to 2.5 mg (half a 5-mg tablet) twice a day depending on the patient's heart rate and symptoms. In patients over 75 years old, a lower starting dose of 2.5 mg twice a day can be used. Treatment must be stopped if the heart rate is persistently below 50 beats per minute or if symptoms of bradycardia (slow heart rate) continue. When used for angina, treatment should be stopped if symptoms do not improve after 3 months. Also, the doctor will consider stopping treatment if the medicine has only a limited effect on reducing symptoms or reducing the heart rate.

How does Ivabradine Accord work?

The symptoms of angina are caused by the heart muscle not receiving enough oxygenated blood. In stable angina, these symptoms occur during physical effort. The active substance in Ivabradine Accord, ivabradine, blocks the 'I_f current' in the sinus node, the natural 'pacemaker' that regulates the heart rate. When this current is blocked, the heart rate is lowered, so that the heart has less work to do and needs less oxygenated blood. Ivabradine Accord therefore reduces or prevents the symptoms of angina.

The symptoms of heart failure are caused by the heart not pumping enough blood around the body. By lowering the heart rate, Ivabradine Accord reduces the stress on the heart, thereby slowing the progression of heart failure and improving symptoms.

How has Ivabradine Accord been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Procoralan, and do not need to be repeated for Ivabradine Accord.

As for every medicine, the company provided studies on the quality of Ivabradine Accord. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Ivabradine Accord?

Because Ivabradine Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ivabradine Accord approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Ivabradine Accord has been shown to have comparable quality and to be bioequivalent to Procoralan. Therefore, the CHMP's view was that, as for Procoralan, the benefit outweighs the identified risk. The Committee recommended that Ivabradine Accord be approved for use in the EU.

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

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

Other information about Ivabradine Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Ivabradine Accord on 22 May 2017.

The full EPAR for Ivabradine Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ivabradine Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 05-2017.