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EPAR summary for the public

Ivabradine Zentiva

ivabradine

This is a summary of the European public assessment report (EPAR) for Ivabradine Zentiva. 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 Zentiva.

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

What is Ivabradine Zentiva and what is it used for?

Ivabradine Zentiva 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 a beta-blocker alone.

Ivabradine Zentiva 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 Zentiva contains the active substance ivabradine. It is a 'generic medicine'. This means that Ivabradine Zentiva is similar to 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 Zentiva used?

Ivabradine Zentiva 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 decreases 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 should consider stopping treatment if the medicine has only a limited effect on reducing symptoms or reducing the heart rate.

How does Ivabradine Zentiva work?

The symptoms of angina are caused by the heart not receiving enough oxygenated blood. In stable angina, these symptoms occur during physical effort. The active substance in Ivabradine Zentiva, 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 Zentiva 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 Zentiva reduces the stress on the heart, thereby slowing the progression of heart failure and improving symptoms.

How has Ivabradine Zentiva been studied?

Because Ivabradine Zentiva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Procoralan. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Ivabradine Zentiva?

Because Ivabradine Zentiva 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 Zentiva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Ivabradine Zentiva 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 Zentiva be approved for use in the EU.

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

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

Other information about Ivabradine Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Ivabradine Zentiva on 11 November 2016.

The full EPAR for Ivabradine Zentiva 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 Zentiva, 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 11-2016.