European Medicines Agency

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Procoralan
ivabradine

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Procoralan?
Procoralan is a medicine that contains the active substance ivabradine. It is available as salmon-coloured tablets (oblong: 5 mg; triangular: 7.5 mg). The 5-mg tablets have a score line that enables them to be divided into two equal halves, each containing 2.5 mg ivabradine.

What is Procoralan used for?
Procoralan is used to treat the symptoms of long-term stable angina (pains to the chest, jaw and back, brought on by physical effort and due to problems with the blood flow to the heart). It is used in patients with coronary artery disease (obstruction of the blood vessels that supply the heart) who have a normal sinus rhythm (heartbeat).
Procoralan is used in patients who cannot take or tolerate beta-blockers (another type of medicine to treat angina), or it is used in combination with beta-blockers in patients whose disease is not controlled with beta-blockers and whose heart rate is above 60 beats per minute.
The medicine can only be obtained with a prescription.

How is Procoralan used?
Procoralan is taken twice a day with meals, once in the morning and once in the evening.
The recommended starting dose is 5 mg twice a day, although 2.5 mg twice a day can be used in patients over the age of 75 years, before it is increased to 5 mg twice a day. After three to four weeks of treatment, the dose may be increased to 7.5 mg twice a day depending on the patient's response.

How does Procoralan work?
The symptoms of angina are caused by the heart not receiving enough oxygenated blood. In stable angina, these symptoms appear during physical effort. The active substance in Procoralan, ivabradine, works by blocking the 'I_f currents' in the sinus node, the 'pacemaker' for the heart that controls the heart contractions and regulates heart rate. When these currents are blocked, the heart rate is lowered, so the heart has less work to do and needs less oxygenated blood. Procoralan therefore reduces or prevents the symptoms of angina.

How has Procoralan been studied?
Procoralan has been studied in five main studies involving over 4,000 patients with long-term stable angina. The medicine was compared with placebo (a dummy treatment) in 360 patients, atenolol (a

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beta-blocker) in 939 patients or amlodipine (another medicine used to treat angina) in 1,195 patients. It was also compared with placebo as an 'add-on' to atenolol in 889 patients and as an add-on to amlodipine in 728 patients. The main measure of effectiveness was how long the patients could exercise on a bicycle or treadmill, measured at the start and end of each study.

What benefit has Procoralan shown during the studies?
Procoralan was more effective than placebo at improving exercise capacity and was as effective as atenolol and amlodipine. Procoralan was also more effective than placebo when added to atenolol. However, adding Procoralan to amlodipine did not provide an additional benefit.

What is the risk associated with Procoralan?
The most common side effect with Procoralan (seen in more than 1 patient in 10) is luminous phenomena or 'phosphenes' (a temporary brightness in the field of vision). For the full list of all side effects reported with Procoralan, see the Package Leaflet.
Procoralan should not be used in people who may be hypersensitive (allergic) to ivabradine or any of the other ingredients. It must not be used in patients who have a resting heart rate below 60 beats per minute, very low blood pressure, various types of heart disorder (cardiogenic shock, rhythm disorders, heart attack or heart failure) or severe liver problems. It must not be used in women who are pregnant or breast-feeding. For the full list of restrictions, see the Package Leaflet.

Why has Procoralan been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that Procoralan has sufficient effectiveness against angina and an acceptable safety profile for it to provide an alternative treatment for patients who cannot take beta-blockers or whose disease is not controlled with them. The Committee decided that Procoralan's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Procoralan:
The European Commission granted a marketing authorisation valid throughout the European Union, for Procoralan to Les Laboratoires Servier on 25 October 2005. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Procoralan is available here.

This summary was last updated in 12-2009.