8 May 2014
EMA/280865/2014

Review of Corlentor/Procoralan started

The European Medicines Agency has started a review of the medicine Corlentor/Procoralan (ivabradine). Corlentor/Procoralan is used to treat the symptoms of adults with long-term stable angina (chest pain due to obstruction in the arteries in the heart) or long-term heart failure (when the heart cannot pump enough blood to the rest of the body).

The review follows preliminary results from the SIGNIFY study, which was evaluating whether treatment with Corlentor/Procoralan in patients with coronary heart disease reduces the rate of cardiovascular events (such as heart attack) when compared with placebo (a dummy treatment). Patients in the study received up to 10 mg twice daily, which is higher than the currently authorised maximum daily dose (7.5 mg twice daily), and the results showed a small but significant increase in the combined risk of cardiovascular death or non-fatal heart attack with the medicine in a subgroup of patients who had symptomatic angina (Canadian Cardiovascular Society class II - IV).

The European Medicines Agency will now evaluate the impact of the data from the SIGNIFY study on the balance of benefits and risks of Corlentor/Procoralan and issue an opinion on whether the marketing authorisation should be maintained, varied, suspended or withdrawn across the EU.

While the review is ongoing and pending further communication, patients should speak to their doctor or pharmacist if they have any questions or concerns.

More about the medicines

Corlentor and Procoralan are identical medicines that contain the active substance ivabradine. Corlentor/Procoralan is used to treat symptoms of long-term stable angina (chest pain due to obstruction in the arteries in the heart) in adults with coronary heart disease (disease of the heart caused by the obstruction of the blood vessels that supply blood to the heart muscle) who have a normal heart rhythm. Corlentor/Procoralan is also used in patients with long-term heart failure (when the heart cannot pump enough blood to the rest of the body) who have a normal heart rhythm but whose heart rate is at least 75 beats per minute.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Corlentor/Procoralan is available as tablets. It works by lowering the heart rate thereby reducing the stress on the heart and slowing the progression of heart failure and reducing or preventing the symptoms of angina.

Corlentor/Procoralan received an EU-wide marketing authorisation on 25 October 2005.

More about the procedure

The review of Procoralan/Corlentor has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion.