15 September 2016
EMA/CHMP/603734/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ivabradine Zentiva

ivabradine

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ivabradine Zentiva, intended for the treatment of chronic heart failure and symptomatic treatment of chronic stable angina pectoris. The applicant for this medicinal product is Zentiva, k.s.

Ivabradine Zentiva will be available as 5 mg and 7.5 mg film-coated tablets. The active substance of Ivabradine Zentiva is ivabradine, a heart rate lowering agent (ATC code: C01EB17) that acts by selective and specific inhibition of the cardiac pacemaker I_f current that controls the spontaneous diastolic depolarisation in the sinus node and regulates heart rate.

Ivabradine Zentiva is a generic of Procoralan, which has been authorised in the EU since the 25 October 2005. Studies have demonstrated the satisfactory quality of Ivabradine Zentiva and its bioequivalence to the reference product Procoralan. A question and answer document on generic medicines can be found here.

The full indication is:

"Symptomatic treatment of chronic stable angina pectoris

Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 beats per minute (bpm). Ivabradine is indicated:

- in adults unable to tolerate or with a contraindication to the use of β-blockers, or
- in combination with β-blockers in patients inadequately controlled with an optimal β-blocker dose.

Treatment of chronic heart failure

Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including β-blocker therapy or when β-blocker therapy is contraindicated or not tolerated".

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.