23 July 2015
EMA/CHMP/461869/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ivabradine Anpharm

ivabradine

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation based on an informed consent application for the medicinal product Ivabradine Anpharm, intended for the treatment of stable chronic angina pectoris and chronic heart failure. The applicant for this medicinal product is ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.

Ivabradine Anpharm will be available as 5 mg and 7.5 mg film-coated tablets. The active substance of Ivabradine Anpharm is ivabradine, a heart-rate lowering agent (ATC code: C01EB17).

Ivabradine Anpharm works by blocking the 'I_f currents' in the sinus node, the 'pacemaker' for the heart that controls the heart's contractions and regulates the heart rate. When these currents are blocked, the heart rate is lowered, so that the heart has less work to do and needs less oxygenated blood. Ivabradine Anpharm therefore reduces or prevents the symptoms of angina. By lowering the heart rate, it also reduces the stress on the heart, thereby slowing the progression of heart failure and improving symptoms.

The benefits with Ivabradine Anpharm are its ability to diminish 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 and to slow the progression of heart failure and to improve the symptoms in heart failure.

The most common side effect with Ivabradine Anpharm (seen in more than 1 patient in 10) is luminous phenomena or 'phosphenes' (a temporary brightness in the field of vision) and bradycardia.

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 bpm. Ivabradine is indicated:

- in adults unable to tolerate or with a contra-indication to the use of beta-blockers

[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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- or in combination with beta-blockers in patients inadequately controlled with an optimal betablocker 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 beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated."

It is recommended that the treating physician should be experienced in the management of chronic heart failure.

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.