24 June 2010
EMA/392565/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Brinavess

vernakalant hydrochloride

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Brinavess, 20 mg/ml, concentrate for solution for infusion intended for rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults (for non-surgery patients: atrial fibrillation ≤ 7 days duration; for post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration). The applicant for this medicinal product is Merck Sharp & Dohme Ltd.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Brinavess is vernakalant hydrochloride a novel anti-arrhythmic drug that acts preferentially in the atria (ATP code: C01BG11) to prolong atrial refractoriness and to rate-dependently slow impulse conduction.

The benefits with Brinavess are its ability to rapidly convert atrial fibrillation to sinus rhythm. The most common side effects seen in the first 24 hours after receiving Brinavess were dysgeusia (taste disturbance), sneezing and paraesthesia. Serious side effects, including hypotension, bradycardia and complete AV block occurred infrequently. The arrhythmogenic potential of vernakalant appears limited but more information on this potential will be collected from a Post-authorisation Registry study.

A pharmacovigilance plan for Brinavess will be implemented as part of the marketing authorisation.

The approved indication is: "Rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults:

- for non-surgery patients: atrial fibrillation ≤ 7 days duration;
- for post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration."

[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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It is proposed that Brinavess is administered by intravenous infusion, by qualified medical personnel in a monitored clinical setting appropriate for cardioversion. Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC), which will be published in the European Public Assessment Report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Brinavess and therefore recommends the granting of the marketing authorisation.