17 February 2011
EMA/CHMP/131489/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Brinavess

vernakalant hydrochloride

On 17 February 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Brinavess. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Ltd. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to a contraindication as follows:

"Use of intravenous rhythm control anti-arrhythmics (class I and class III) within 4 hours prior to, **as well as in the first 4 hours after**, Brinavess administration."

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

For information, the full contraindications for Brinavess will be as follows[2]:

- "Hypersensitivity to the active substance or to any of the excipients (see section 6.1).
- Patients with severe aortic stenosis, patients with systolic blood pressure < 100 mm Hg, and patients with heart failure class NYHA III and NYHA IV.
- Patients with prolonged QT at baseline (uncorrected > 440 msec), or severe bradycardia, sinus node dysfunction or second degree and third degree heart block in the absence of a pacemaker.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

[2] The text in bold represents the new or the amended contraindication.

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

- Use of intravenous rhythm control anti-arrhythmics (class I and class III) within 4 hours prior to, **as well as in the first 4 hours after**, Brinavess administration.
- Acute coronary syndrome (including myocardial infarction) within the last 30 days.″