EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name:VERNAKALANT HYDROCHLORIDE

Procedure No. EMEA/H/C/PSUSA/00003109/201408

Period covered by the PSUR: 1 September 2013 – 31 August 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for VERNAKALANT HYDROCHLORIDE, the scientific conclusions of CHMP are as follows:

Based on three reported cases of atrial flutter with 1:1 atrioventricular condition (two literature cases and one from the SPECTRUM post-authorisation safety study), SmPC sections 4.8 and 4.4 - subsection 'Atrial Flutter' is updated. The objective of the update is to highlight the occurrence of these very rare cases in the post-marketing setting.

Therefore, in view of available data regarding vernakalant the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for VERNAKALANT HYDROCHLORIDE the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing VERNAKALANT HYDROCHLORIDE is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.