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Committee for Medicinal Products for Human Use (CHMP)

Votubia

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

International non-proprietary name: everolimus

Procedure No.: EMEA/H/C/002311/PSUV/0022

Period covered by the PSUR: 01.04.13 - 30.09.13

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Scientific conclusions

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

Late breaking-information was received by the PRAC: Following an FDA-alert and notification by the Swedish agency, new information concerning increased risk for angioedema when combining mTOR inhibitors with angiotensin converting enzyme (ACE) inhibitors was received. Strong evidence for a causal relationship was provided. Therefore, in view of available data regarding drug-drug interaction, the PRAC considered that changes to the product information were warranted.

The corresponding section of the RMP on drug-drug interaction should also be updated when the next update of a RMP is submitted.

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 Votubia, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance EVEROLIMUS is favourable subject to the proposed changes to the product information.

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