23 October 2014
EMA/CHMP/795884/2014
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/0025

Period covered by the PSUR: 1 October 2013 – 30 March 2014

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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:

During the reporting period of this PSUR, the MAH also performed a review of cases of pneumocystis jirovecii pneumonia (PJP, PCP) following request of the FDA to update the labeling information of everolimus. Cases of PJP/PCP, some with fatal outcome, have been reported in patients who received everolimus. Thus the MAH proposed changes also for the EU SmPC, to which the PRAC agreed.

Therefore, in view of available data regarding PJP/PCP, 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 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.