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: temozolomide

Procedure No. EMEA/H/C/PSUSA/00002886/201407

Period covered by the PSUR: 13 July 2011 – 12 July 2014

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Scientific conclusions

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

Cumulative review of the data for cytomegalovirus infection, hepatitis B, herpes simplex, herpes zoster and tuberculosis has revealed cases of reactivation of cytomegalovirus infection and hepatitis B. Evaluation of further safety reports of cytomegalovirus infection revealed that also primary in addition to reactivated cytomegalovirus infections cannot be ruled out. Furthermore, three fatal cases of hepatitis B reactivation were additionally retrieved from the database. Therefore updated information on hepatitis B reactivation including fatal outcome should be included in the product information for temozolomide.

In addition, further to a signal work-up for diabetes insipidus, four out of five literature reports lead to a possible association with temozolomide therapy, therefore the product information should be updated accordingly.

Therefore, in view of available data regarding temozolomide, 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 temozolomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing temozolomide is favourable subject to the proposed changes to the product information

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