



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/602813/2015
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: verteporfin

Procedure No. EMEA/H/C/PSUSA/00003110/201412

Period covered by the PSUR: 01 January 2014 – 31 December 2014



Scientific conclusions

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

At the request of PRAC, the MAH submitted a cumulative review of convulsion cases. Seventeen cases were reported cumulatively (including 4 with a confirmed clinical diagnosis), mostly in relation to vasovagal reactions which is already listed in the PI together with hypersensitivity reactions. The product information currently states that both vasovagal and hypersensitivity reactions are associated with related general symptoms (e.g. syncope, sweating, dizziness, rash, dyspnoea, flushing and changes in blood pressure and heart rate). Therefore, in view of available data regarding convulsions associated with vasovagal conditions, 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 verteporfin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing verteporfin 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.