EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2015
EMA/CHMP/516204/2015
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: eslicarbazepine acetate

Procedure No. EMEA/H/C/PSUSA/00001267/201410

Period covered by the PSUR: 22 October 2013 – 21 October 2014

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Scientific conclusions

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

Based on dermatological expert evaluation of case reports with suspected Serious Cutaneous Adverse Reactions, the PRAC was of the opinion that the Summary of Product Characteristics (SmPC) should be updated to include information on Serious Cutaneous Adverse Reactions. The Package Leaflet should be updated accordingly.

In addition, two post-marketing surveillance cases of atrioventricular block complete have been reported. Although the signal evaluation of this topic is ongoing, the PRAC recommended the deletion of the sentence “No second or higher degree AV block was seen in ESL-treated patients” from section 4.8 of the SmPC.

Therefore, in view of available data regarding eslicarbazepine acetate, 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 eslicarbazepine acetate the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing eslicarbazepine acetate is favourable subject to the proposed changes to the product information

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