EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): eslicarbazepine acetate

Procedure No. EMEA/H/C/PSUSA/00001267/201810

Period covered by the PSUR: 22/10/2015 to 21/10/2018

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Scientific conclusions

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

Weight gain

Taking into account that more eslicarbazepine acetate-treated patients experienced weight increase than weight decrease during the open label extension of the Phase III studies the current labelling is not considered adequate. In addition, there are six post-marketing cases of 'weight increase' for which the causality was assessed as possibly related to eslicarbazepine acetate by the MAH. Considering that changes in body weight can influence the treatment decision and are of particular importance in epilepsy which itself may be associated with overweight/obesity this information should adequately be reflected in SmPC and PIL.

Based on this outcome, update of section 4.8 of the SmPC to add 'weight increased' with the frequency common (calculation based on clinical trial data) is recommended.

Overdose

During the reporting period, the MAH detected a signal of **overdose**. Two clusters of ADRs were identified in context of overdose cases – epilepsy/seizures/status epilepticus and cardiac events, mainly arrhythmias. The information currently provided in section 4.9 of the SmPC is limited and does not reflect a potential cardiac risk of eslicarbazepine acetate overdose or the risk of seizure induction. Based on this outcome, update of section 4.9 to reflect new information from overdose cases is recommended.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing eslicarbazepine acetate were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for eslicarbazepine acetate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing eslicarbazepine acetate is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.