



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): perampanel

Procedure No. EMEA/H/C/PSUSA/00009255/201707

Period covered by the PSUR: 23 January 2017 to 22 July 2017



Scientific conclusions

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

Drug reaction with eosinophilia and systemic symptoms (DRESS) in association with perampanel use was first reported in a PSUR in 2014. This case concerned a 13- year- old girl who presented with DRESS after increasing the dose of perampanel from 4 to 8 mg and developed acute respiratory distress and required mechanical ventilation and vasopressors, methylprednisolone and IV immunoglobulin. The patient improved after all antiepileptics were stopped. Skin biopsy confirmed DRESS. As this was the index case the issue of DRESS has been kept under close review at all subsequent PSURs. This second case of DRESS that is reported within this PSUR period in the 10 year old has several possible confounding factors but an association with perampanel exposure cannot be rule out particularly given the TWO positive rechallenges. We now have two cases of DRESS and there is already class labelling for serious cutaneous adverse reactions for antiepileptics. Taking into account the totality of data available on the association between perampanel and serious skin reactions it is concluded there is sufficient data to warrant an update of sections 4.4 and 4.8 of the SmPC and the package leaflet to reflect the risk of DRESS.

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 perampanel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing perampanel 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.