



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): brivaracetam

Procedure No. EMEA/H/C/PSUSA/00010447/201607

Period covered by the PSUR: 15/01/2016-14/07/2016





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Scientific conclusions

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

Signal: type I hypersensitivity was identified and confirmed for Briviact during the reporting period.

On medical review, 9 cases were suggestive for Type I hypersensitivity. Six out of the 9 cases related to skin manifestations (pruritus [3], erythema [1], rash[1], and urticaria [1]). The remaining cases reported chest discomfort, dyspnea, and flushing, respectively. Four out of the 9 cases were more suggestive that the cause was a Type I hypersensitivity reaction (dyspnea, pruritus (2), urticaria). The events are uncommon and have generally been of mild intensity.

In the view of the data presented in this PSUR, the PRAC Rapporteur considered that changes to the product information of Briviact were warranted. Based on the safety review the PRAC Rapporteur considers that product information update is necessary in order to add safety information regarding the risks of type I hypersensitivity.

In the context of the variation to the terms of the marketing authorization, additional details have added to the text about third BRV metabolite (hydroxy acid) presented in section 5.2 of SmPC.

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

