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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): flutemetamol (^{18}F)

Procedure No. EMEA/H/C/PSUSA/00010293/201510

Period covered by the PSUR: 01 May 2015 to 30 October 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for flutemetamol (^{18}F), the scientific conclusions of the CHMP are as follows:

"In view of the cumulative safety data provided, the terms of the marketing authorisation should be varied by updating section 4.8 of the SmPC and the corresponding safety section 4 of the Package Leaflet in order to downgrade the ADRs 'nausea' and 'chest discomfort' from frequency category 'common' to 'uncommon', and to update section 4.8 of the SmPC to reflect that the overall safety profile is based on data from its administrations to a total of 831 subjects. Therefore, in view of the cumulative data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing flutemetamol (^{18}F) 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 flutemetamol (^{18}F) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing flutemetamol (^{18}F) 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.