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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): gadopiclenol

Procedure No. EMEA/H/C/PSUSA/00000232/202403

Period covered by the PSUR:
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Annex IV

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Scientific conclusions

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

In view of available data on administration during pregnancy and in view of available data on intrathecal administration from the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between gadopiclenol and risks due to use during pregnancy and intrathecal administration is at least a reasonable possibility. The PRAC concluded that the product information of products containing gadopiclenol should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for gadopiclenol the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing gadopiclenol 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.