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): dexmedetomidine

Procedure No. EMEA/H/C/PSUSA/00000998/201703

Period covered by the PSUR: 16 March 2016 to 15 March 2017

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Scientific conclusions

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

The MAH undertook a full cumulative review of case reports of polyuria, identified by the search of polyuria and related PTs, taking into consideration temporal relationship, dose, age, and use.

Based on the association of polyuria with induction of dexmedetomidine infusion, and reports of recovery after discontinuation of dexmedetomidine representing positive dechallenge, the data are supportive of a causal association.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing dexmedetomidine 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 dexmedetomidine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexmedetomidine 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.