14 October 2021
EMA/774698/2021
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/00000998/202103

Period covered by the PSUR: 16 March 2020 To: 15 March 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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:

In view of available data on diabetes insipidus from the literature, spontaneous reports including in several cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dexmedetomidine and diabetes insipidus is established. The PRAC concluded that the product information of products containing dexmedetomidine should be amended.

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.