17 October 2024
EMA/552364/2024
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): esketamine (for centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010825/202403

Period covered by the PSUR: 05 March 2023 To: 04 March 2024

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Scientific conclusions

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

In view of available data on bradycardia and seizure from clinical trial(s), spontaneous reports, including cases with a close temporal relationship, a positive de-challenge and re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between esketamine (nasal) and bradycardia and seizure is at least a reasonable possibility. The PRAC concluded that the product information of products containing esketamine (nasal) 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 esketamine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing esketamine 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.