20 May 2021
EMA/152944/2023
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): vortioxetine

Procedure No. EMEA/H/C/PSUSA/00010052/202009

Period covered by the PSUR: 29 September 2019 to 29 September 2020

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Scientific conclusions

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

In view of available data on headache, hyperhidrosis and hyperprolactinaemia from clinical trials and/or spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action for hyperhidrosis, the PRAC considers a causal relationship between vortioxetine and headache, hyperhidrosis and hyperprolactinaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing vortioxetine should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reactions headache and hyperprolactinaemia with a frequency not known, and hyperhidrosis with a frequency common. The Package leaflet is updated accordingly.

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 vortioxetine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing vortioxetine 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.