19 September 2024
EMA/49924/2025
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): daridorexant

Procedure No. EMEA/H/C/PSUSA/00010993/202401

Period covered by the PSUR: 07 July 2023 To: 06 January 2024

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

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

In view of available data on hypersensitivity, abnormal dreams, nightmares and somnambulism from spontaneous and solicited reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between daridorexant and hypersensitivity (including rash, urticaria) and abnormal dreams, nightmares and somnambulism is at least a reasonable possibility. The PRAC concluded that the product information of products containing daridorexant 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 daridorexant the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing daridorexant 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.