14 November 2024
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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): vardenafil

Procedure No. EMEA/H/C/PSUSA/00003098/202403

Period covered by the PSUR: 05 March 2019 to 04 March 2024

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Scientific conclusions

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

In view of available data on serous central chorioretinopathy and hypersensitivity regarding Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) from the literature, spontaneous reports including in some 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 vardenafil and serous central chorioretinopathy and Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) is at least a reasonable possibility. In addition, visual defects, including central serous chorioretinopathy (CSCR), and cases of non-arteritic ischemic optic neuropathy (NAION) have been reported in connection with the intake of vardenafil and other PDE5 inhibitors. The PRAC concluded that the product information of products containing vardenafil 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 vardenafil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing vardenafil 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.