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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/00003098/201903

Period covered by the PSUR: from 04 March 2016 to 04 March 2019

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Scientific conclusions

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

Central nervous system haemorrhages and cerebrovascular accidents (CVA) have been monitored in the last PSURs. An additional analysis, including data from clinical trials, post marketing experience and literature showed that some occurred with a close temporal association (the two first weeks) after the intake of vardenafil. Therefore, the current information of section 4.8 should be revised to highlight the temporal association with vardenafil. In addition, in line with the product information of other PDE5s, a warning should also be included in section 4.4 to highlight these events, and reflect that it is not possible to definitively determine whether these events are related directly to any risk factors, to vardenafil, to sexual activity, or to a combination of these or other factors.

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 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.