EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: brimonidine (centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010093/201502

Period covered by the PSUR: 22 August 2014 – 21 February 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for brimonidine (centrally authorised product only), the scientific conclusions of CHMP are as follows:

Haemodynamic effects

Although no new cases were identified in the reporting interval, more information has been provided on some of the previously identified cases. Given that there are at least three cases with implied rechallenge strongly suggestive of a haemodynamic effect (particularly hypotension and related symptoms) associated with the application of Mirvaso, as well as other suggestive cases, it is considered that there is sufficient evidence to warrant an update of the product information to inform prescribers and patients of the risk of haemodynamic effects with Mirvaso.

Angioedema

Two cases in the current reporting period reported face/tongue swelling in association with other symptoms suggestive of systemic allergic reaction. In the previous reporting period, 4 cases involving lip and/or tongue swelling, throat or chest tightening, or difficulty breathing were considered suggestive of angioedema. Although the term angioedema was not specifically reported in any cases, the PRAC considered that a causal relationship between Mirvaso and the adverse event is at least a reasonable possibility. There was now a cumulative total of 6 cases with features strongly suggestive of angioedema.

Therefore, in view of available data regarding haemodynamic effects and angioedema, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for brimonidine (centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing brimonidine (centrally authorised product only) is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.