15 September 2016
EMA/621470/2016
Committee for Medicinal Products for Human Use (CHMP)

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

Active substance: brimonidine (centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010093/201602

Period covered by the PSUR: 22 August 2015 to 21 February 2016

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Scientific conclusions

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

Within the four clinical studies discussed in this PUSA, 'pallor' or 'over-whitening of the skin' has been reported. The data indicates that between 3.9% to 18.9% of patients reported too much whitening, with between 0% to 9.3% of patients indicating that they were bothered by too much whitening.

Cumulatively 119 post-marketing cases of pallor and skin discolouration have been reported. In 5 cases pallor was associated with systemic events such as hypotension which is already an identified adverse drug reaction of Mirvaso. In 114 cases there were no associated systemic events and these cases appear to represent a localised over-whitening effect. Only 1 case of pallor associated with the recommended use of Mirvaso was considered to be serious by the MAH. The majority of cases were associated with additional adverse drug reactions such as erythema, flushing, skin burning sensation, condition aggravated and rash. Nineteen (19) of the cases of localised pallor were not associated with any other adverse events; only 5 out of these 19 patients discontinued treatment as a result of the pallor.

Therefore, in view of available data regarding pallor and over-whitening, the PRAC considered that changes to the product information are warranted.

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 brimonidine (centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brimonidine (centrally authorised product only) 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.