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

Procedure No. EMEA/H/C/PSUSA/00010093/201408

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

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for brimonidine, the scientific conclusions of CHMP are as follows:

A large number of spontaneous reports of aggravation of symptoms of rosacea, such as erythema and flushing have been reported in the postmarketing setting. Some cases were reported as a 'rebound' effect. The analysis of time to onset of symptoms was suggestive of an association with brimonidine; they usually occur within the first days of treatment and when specified, within few hours after drug application, suggesting causal relationship with brimonidine, which was also confirmed by the observed positive de-challenges. Therefore, in view of available data regarding the new important identified risk "Condition aggravated (erythema, flushing, skin burning sensation)", the PRAC considered that changes to the product information were warranted.

In addition, the cumulative search in the pharmacovigilance database to identify cases with terms suggestive of systemic allergic reactions revealed that a significant number of such cases have been reported. At least 4 cases have been identified with features of a systemic allergic reaction and strong evidence of a causal relationship with brimonidine and therefore, the PRAC considered appropriate to update the information for prescribers and patients. A number of cases of localised facial swelling were also identified. Therefore, in view of available data regarding the important potential risk "systemic allergic reaction", 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 the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing brimonidine is favourable subject to the proposed changes to the product information

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