15 November 2018
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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): bimatoprost

Procedure No. EMEA/H/C/PSUSA/00000413/201803

Period covered by the PSUR: 08 March 2015 - 07 March 2018

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Scientific conclusions

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

During the reporting period of this PSUR, a number of cases from routine pharmacovigilance activities were reported with positive dechallenge and/or rechallenge combined with a plausible mode of action and indicated a causal relationship with the use of bimatoprost containing medicinal products.

Based on the available data presented in this PSUR, the PRAC considered that the SmPC (section 4.8) and Package Leaflet accordingly for:

- bimatoprost 0.01% formulations should be amended to reflect the following adverse drug reactions: dizziness, hypertension, photophobia, skin discoloration (periocular), and ocular discomfort. The frequency cannot be calculated based on the available data and therefore included as “not known”.

- bimatoprost 0.03% formulations should be amended to reflect the following adverse drug reactions: ocular discomfort and skin discoloration (periocular). The frequency cannot be calculated based on the available data and therefore included as “not known”.

- bimatoprost 0.03% PF should be amended to reflect the following adverse drug reactions: dizziness, hypertension, skin discoloration (periocular), ocular discomfort and eye discharge. The frequency cannot be calculated based on the available data and therefore included as “not known”.

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 bimatoprost the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bimatoprost 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.