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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): brinzolamide

Procedure No. EMEA/H/C/PSUSA/00000432/202108

Period covered by the PSUR: 01 September 2016 To: 31 August 2021

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Scientific conclusions

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

In view of available data on Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) from spontaneous reports including several cases highly suggestive of causal association with brinzolamide, and the fact that topical brinzolamide is absorbed systemically, and therefore, the same types of ADRs (including SJS and TEN) associated with sulphonamides may occur with topical administration, the PRAC Rapporteur considers a causal relationship between brinzolamide and SJS/TEN is at least a reasonable possibility. Therefore, an update of sections 4.4 and 4.8 of the SmPC to add the ADR SJS/TEN with a frequency 'not known' and a warning on SJS/TEN is considered warranted. The Package leaflet should be updated accordingly.

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