EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): bosentan

Procedure No. EMEA/H/C/PSUSA/00000425/201511

Period covered by the PSUR: 20 November 2014 to 19 November 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Literature suggests a physiologic role of endothelin in ocular blood flow regulation. Blurred vision is listed in the product information of ambrisentan (selective Endothelin receptor type A (ETA) antagonist) as an adverse drug reaction and it is considered as an ongoing signal for macitentan (both ETA and ETB antagonist). In addition, a well-documented case with positive rechallenge of a direct effect of bosentan in accommodation (although the ophthalmologist suggested that the event appeared to have affected ocular motility rather than vision) was noted. Even if blurred vision appears to be a symptom of systemic hypotension in most reported cases, the PRAC considers that systemic hypotension induced by bosentan may have a functional impact on eyes. Prescribers and patients should be adequately informed about this risk.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing bosentan were warranted.

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

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for bosentan the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing bosentan is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.