



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): acridinium bromide

Procedure No. EMEA/H/C/PSUSA/00009005/201607

Period covered by the PSUR: 21 January 2016 to 20 July 2016



Scientific conclusions

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

Based on 3 cumulative spontaneous post marketing reports of anaphylactic reaction (all serious), the MAH proposes to add anaphylactic reaction to section 4.8 (Undesirable effects) of the SmPC with a frequency of 'not known'.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing acridinium bromide were 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 acridinium bromide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing acridinium bromide 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.