



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): midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)

Procedure No. EMEA/H/C/PSUSA/00010118/202209

Period covered by the PSUR: 09 September 2019 To: 09 September 2022



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures), the scientific conclusions of the CHMP are as follows:

In view of available data on anaphylactic reaction from spontaneous reports including two cases reporting anaphylactic reaction *while* receiving treatment with Buccolam oromucosal solution or in connection with a buccal administration of midazolam, both suggesting a temporal relation, and in view of the listedness of anaphylactic shock as ADR in the SmPC of midazolam containing products of other formulations, the PRAC considers a causal relationship between midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures) and anaphylactic reaction is at least a reasonable possibility.

The PRAC concluded that the product information of products containing midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures) should be amended 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 midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures) 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.