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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/00010118/201909

Period covered by the PSUR: 10 September 2016 to 9 September 2019

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**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 CHMP are as follows:

In view of available data on events of oedema/swelling from spontaneous reports with use of Buccolam including some cases with a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures) and angioedema 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.