



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2024
EMA/186543/2024
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): tedizolid phosphate

Procedure No. EMEA/H/C/PSUSA/00010369/202306

Period covered by the PSUR:
20 June 2020 To: 20 June 2023



Scientific conclusions

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

In view of available data on serotonin syndrome from the literature and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between tedizolid phosphate and serotonin syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing tedizolid phosphate should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for tedizolid phosphate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tedizolid phosphate 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.