EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2022
EMA/816905/2022
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): para-aminosalicylic acid (centrally authorised product)

Procedure No. EMEA/H/C/PSUSA/00010171/202110

Period covered by the PSUR: 07/10/2018 to 07/10/2021



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**Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for para-aminosalicylic acid (centrally authorised product), the scientific conclusions of CHMP are as follows:

In view of available data on the literature (Parvez et al.) including a study reporting that the para-aminosalicylic acid-calcium formulation significantly reduced systemic exposure to tenofovir, it is considered that such information may be important to prescribers since the data appears to be of reasonable quality with an acceptable cross-over design, and the effect size is very large. In addition, there is no obvious reason why another salt form than that approved would drastically change the interaction potential. Therefore, it is concluded that the product information of products containing para-aminosalicylic acid (centrally authorised product) 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 para-aminosalicylic acid (centrally authorised product) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing para-aminosalicylic acid (centrally authorised product) 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.