



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): conestat alpha

Procedure No. EMEA/H/C/PSUSA/00000873/201610

Period covered by the PSUR: 29 April 2015 to 28 October 2016



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for conestat alfa, the scientific conclusions of CHMP are as follows:

The PRAC noted the data from the post-authorisation phase 1 skin prick study C1 1113, which showed that none of the ten patients with cow's milk allergy had experienced allergic reactions to Ruconest when administered skin prick test, intracutaneous test and subcutaneous challenge doses of Ruconest and that the likelihood of cross-reactivity to host-related impurities thus appears to be low. The PRAC also noted that it was agreed in the context of the Ruconest variation procedure II/32 that measurement of immunoglobulin E to detect patients with rabbit allergy was unnecessary prior to receipt of Ruconest. Taking into account all available data for Ruconest, the PRAC therefore considered that the Ruconest product information should be revised to remove the advice on performing skin prick tests for cross-reactivity with cow's milk from section 4.4 of the SmPC and to remove the requirement for inclusion of information about a skin prick test protocol for possible risk of cross-reactivity in patients with cow's milk allergy from the educational material in Annex IID.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for conestat alfa, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing conestat alfa is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.