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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): fosaprepitant

Procedure No. EMEA/H/C/PSUSA/00001471/201603

Period covered by the PSUR: 26 March 2015 to 25 March 2016

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Scientific conclusions

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

During the interval 8 cases of anaphylactic shock have been reported, 19 cases cumulatively. Two of the 19 cases, both reporting anaphylactic shock, presented without confounding factors. Based on the case analysis an update of sections 4.4 and 4.8 of the Summary of product characteristic to include information on anaphylactic reactions and shock is recommended.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing fosaprepitant were warranted.

The important identified risk of hypersensitivity is recommended to be updated with information on anaphylactic reactions/shock; this change can be implemented at the next regulatory opportunity requiring an update of the RMP.

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 fosaprepitant the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fosaprepitant 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.