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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): ceftaroline fosamil

Procedure No. PSUSA/00010013/202410

Period covered by the PSUR: 29 October 2021 to 28 October 2024

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Scientific conclusions

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

In view of available data on severe cutaneous adverse reactions (SCARs) from the literature and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ceftaroline fosamil and drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) is at least a reasonable possibility. The PRAC concluded that the product information of products containing ceftaroline fosamil 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 ceftaroline fosamil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ceftaroline fosamil 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.