



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 April 2017
EMA/321854/2017
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): daptomycin

Procedure No. EMEA/H/C/PSUSA/00000931/201609

Period covered by the PSUR: 12 Sep 2015 to 11 Sep 2016



Scientific conclusions

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

A cumulative review of post-marketing data revealed that there were a total of 17 cases where the reporter described organising pneumonia associated with daptomycin therapy without reporting an associated diagnosis of pulmonary eosinophilia or eosinophilic pneumonia. The majority describe probable or possible organising pneumonia based on a radiographic presentation compatible with eosinophilic pneumonia. Definite cases with both histopathological and radiographic descriptions appeared to be consistent with the known presentation of eosinophilic pneumonia, but the diagnosis was not initially recognised. Organising pneumonia is therefore to be added to section 4.4 of the EU SmPC (special warnings and precautions) and to section 4.8 (undesirable effects) as an adverse reaction of not known frequency under respiratory, thoracic and mediastinal disorders. No changes to the package leaflet are required.

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