26 January 2017
EMA/CHMP/37961/2017
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Daptomycin Hospira

daptomycin

On 26 January 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Daptomycin Hospira, intended for the treatment of complicated skin and soft tissue infections (cSSTI), right-sided infective endocarditis (RIE) due to *Staphylococcus aureus* and *S. aureus* bacteraemia associated with RIE or with cSSTI. The applicant for this medicinal product is Hospira UK Limited.

Daptomycin Hospira will be available as a powder for solution for injection/infusion (350 mg and 500 mg). The active substance of Daptomycin Hospira is daptomycin, a cyclic lipopeptide active against Gram-positive bacteria only (ATC code: J01XX09). Daptomycin binds to bacterial membranes, causing rapid inhibition of protein, DNA, and RNA synthesis, resulting in bacterial cell death.

Daptomycin Hospira is a generic of Cubicin, which has been authorised in the EU since 19 January 2006. Studies have demonstrated the satisfactory quality of Daptomycin Hospira. Since Daptomycin Hospira is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product was not required. A question and answer document on generic medicines can be found here.

The full indication is:

"Daptomycin Hospira is indicated for the treatment of the following infections (see sections 4.4 and 5.1).

- Adult and paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections (cSSTI).
- Adult patients with right-sided infective endocarditis (RIE) due to Staphylococcus aureus. It is recommended that the decision to use daptomycin should take into account the antibacterial susceptibility of the organism and should be based on expert advice (see sections 4.4 and 5.1).
- Adult patients with Staphylococcus aureus bacteraemia (SAB) when associated with RIE or with cSSTI.

Daptomycin is active against Gram-positive bacteria only (see section 5.1). In mixed infections where Gram-negative and/or certain types of anaerobic bacteria are suspected, daptomycin should be co-administered with appropriate antibacterial agent(s).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Consideration should be given to official guidance on the appropriate use of antibacterial agents."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.