



12 October 2017
EMA/CHMP/664609/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Cubicin daptomycin

On 12 October 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Cubicin. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The CHMP adopted an extension to an existing indication to include treatment of²:

Adult and paediatric (1 to 17 years of age) patients with *Staphylococcus aureus* bacteraemia (SAB)-when associated with RIE or with cSSTI. In adults, use in bacteraemia should be associated with RIE or with cSSTI, while in paediatric patients, use in bacteraemia should be associated with cSSTI.

For information, the full indications for Cubicin will be as follows:

“Cubicin 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 and paediatric (1 to 17 years of age) patients with *Staphylococcus aureus* bacteraemia (SAB). In adults, use in bacteraemia should be associated with RIE or with cSSTI, while in paediatric patients, use in bacteraemia should be associated 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, Cubicin should be co-administered with appropriate antibacterial agent(s).

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

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

² **New text in bold, removed text as strikethrough**



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