

## Cubicin® (daptomycin) - First-Time Generic

- On September 15, 2016, <u>Teva announced</u> the launch of an authorized generic version of Merck's <u>Cubicin</u> (<u>daptomycin</u>) 500 mg per vial injection.
  - In addition, Hospira and Crane received FDA approval of AP-rated generic versions of Cubicin on September 12, 2014 and June 15, 2016, respectively.
  - Based on a court decision, Hospira and Crane may have an opportunity to launch their generic Cubicin products in 2016.
- Cubicin is indicated for the treatment of complicated skin and skin structure infections and *Staphylococcus* aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis.
  - Cubicin is not indicated for the treatment of pneumonia.
  - Cubicin is not indicated for the treatment of left-sided infective endocarditis due to S. aureus.
  - Cubicin has not been studied in patients with prosthetic valve endocarditis.
- Daptomycin is also available as <u>Cubicin<sup>®</sup> RF</u>. This formulation may be stored at room temperature, and should be reconstituted with sterile water for injection or bacteriostatic water for injection. In contrast, Cubicin should be stored under refrigeration and reconstituted with 0.9% sodium chloride.
  - Once reconstituted, Cubicin RF has a longer in-use shelf-life compared to Cubicin. Reconstituted Cubicin RF vials may last up to 3 days when refrigerated; syringes or IV bags may last up to 5 days when reconstituted with bacteriostatic water and stored under refrigeration.
  - Cubicin vials and IV bags both have an in-use shelf-life of 12 hours at room temperature and 48 hours when refrigerated.
- According to IMS Health, Cubicin had U.S. sales of approximately \$1.2 billion for 12 months ending in July 2016.



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