



Cubicin[®]/Cubicin[®] RF (daptomycin) – Expanded indication

- On September 1, 2017, the FDA approved Merck's **Cubicin (daptomycin)** and **Cubicin RF (daptomycin)** injections, for the treatment of *Staphylococcus aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).
 - Cubicin/Cubicin RF is also indicated for complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age) and for *S. aureus* bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis.
 - Cubicin/Cubicin RF is not indicated for the treatment of pneumonia.
 - Cubicin/Cubicin RF is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*.
 - Cubicin/Cubicin RF is not recommended in pediatric patients younger than one year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs.
- The expanded indication approval of Cubicin/Cubicin RF was based on a randomized study to treat 73 pediatric patients aged 1 to 17 years with bacteremia. Patients received Cubicin/Cubicin RF or a standard comparator medication for up to 42 days. The clinical outcome was determined by resolution or improvement of symptoms at test-of-cure (TOC) visit, 7 to 14 days after the last dose.
 - The clinical success rates determined at TOC visit were 88% for Cubicin/Cubicin RF and 77% for the comparator.
 - In addition, use of Cubicin/Cubicin RF in the 1 – 17 year age groups is supported by evidence from adequate and well-controlled studies in adults, with additional data from pharmacokinetic (PK) studies in pediatric patients, and from safety, efficacy and PK studies in pediatric patients with cSSSI and *S. aureus* bloodstream infections.
- The most common adverse reactions (≥ 5%) with Cubicin/Cubicin RF use in pediatric patients with *S. aureus* bacteremia were vomiting and elevated creatinine phosphokinase.
- The recommended intravenous dosage of Cubicin/Cubicin RF for pediatric patients (1 to 17 years of age) with *S. aureus* bacteremia is as follows:

Age	Dosage	Duration of Therapy
12 – 17 years	7 mg/kg once every 24 hours infused over 30 minutes	Up to 42 days
7 – 11 years	9 mg/kg once every 24 hours infused over 30 minutes	
1 – 6 years	12 mg/kg once every 24 hours infused over 60 minutes	

- Consult the Cubicin/Cubicin RF drug label for dosing recommendations for other indications in adult and pediatric patients.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at optum.com.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.