Visit cubicinrf.ca for availability and product details

NEW CUBICIN® RF: reformulated with reconstitution and storage in mind.[1*]

- **NEW** – Product storage prior to reconstitution: 15-30°C
- **NEW** – In-the-vial reconstitution diluent requirements
- **NEW** – In-use storage options
- **NEW** – Reconstitution procedure vs. CUBICIN®

*Comparative clinical significance is unknown.

NEW
Product storage prior to reconstitution: 15-30°C

- No refrigeration required[1]

NEW
In-the-vial reconstitution diluent requirements for both[1]

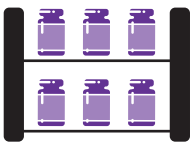
IV Injection
(over a period of 2 min)

IV Infusion†
(over a period of 30 min)

- Reconstitute CUBICIN® RF 500 mg vial with **only** either:‡
  - 10 mL of Sterile Water for Injection, **or**
  - 10 mL of Bacteriostatic Water for Injection (to a concentration of 50 mg/mL)

† For IV Infusion: further dilute into a 50 mL IV infusion bag containing 0.9% sodium chloride for injection to a final concentration in the range of 1 to 14 mg/mL (typically 10 mg/mL).

‡ Do **NOT** use saline based diluents for the reconstitution in the vial because this will result in a hyperosmotic solution that may result in infusion site reactions if the reconstituted product is administered as an intravenous injection over a period of 2 minutes.

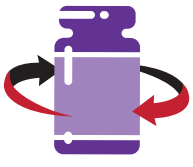


NEW
CUBICIN® RF (reconstituted) offers a variety of in-use storage options[1]

- Glass vial: up to 3 days if refrigerated§
- Sterile Polypropylene Syringe: up to 5 days if refrigerated§
- Polyvinyl Chloride IV Bag: up to 5 days if refrigerated§

§Refer to the Product Monograph, or CUBICINRF.ca, for in-use storage and shelf-life options as they are dependent on container, diluent, and storage temperature (room 20°C - 25°C; or refrigerated 2°C- 8°C) following reconstitution.

The listed shelf-life of reconstituted and diluted solutions of CUBICIN® RF should not be exceeded and all unused portions should be discarded.



NEW
CUBICIN® RF: reconstitution procedure[1]

1. Remove the polypropylene flip-off cap from the CUBICIN® RF vial to expose the central portion of the rubber stopper.
2. Wipe the top of the rubber stopper with an alcohol swab or other antiseptic solution and allow it to dry. After cleaning, the rubber stopper should not be touched or allowed to touch any other surface.
3. Transfer 10 mL of Sterile Water for Injection or Bacteriostatic Water for Injection through the center of the rubber stopper into the CUBICIN® RF vial. Use a beveled sterile transfer needle that is 21 gauge or smaller in diameter, pointing the transfer needle toward the wall of the vial.
4. Rotate or swirl the vial to dissolve the contents for a few minutes, as needed, to obtain a completely reconstituted solution.
5. Slowly remove the reconstituted liquid containing daptomycin (50 mg/mL) from the vial using a beveled sterile needle that is 21 gauge or smaller in diameter.

- Aseptic technique must be used during preparation.
- CUBICIN® RF vials are for single-use only.

INDICATIONS AND CLINICAL USE:

CUBICIN®/CUBICIN® RF is indicated for the following infections in adults:

- **Complicated skin and skin structure infections**[II] caused by susceptible strains of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus pyogenes* and *Streptococcus agalactiae*.[¥¶]
- ***Staphylococcus aureus* bloodstream infections (bacteremia) including those with right-sided *Staphylococcus aureus* infective endocarditis (native valve)** caused by methicillin-susceptible and methicillin-resistant strains.[¥¶]
  - Patients with prosthetic valves, meningitis, known osteomyelitis, polymicrobial bloodstream infections or with intravascular foreign material not planned for removal within 4 days of dosing (except vascular stents in place for > 6 months or permanent pacemakers) were not enrolled in clinical trials.
  - The efficacy of CUBICIN®/CUBICIN® RF in patients with left-sided infective endocarditis due to *Staphylococcus aureus* has not been demonstrated. The clinical trial of daptomycin in patients with *Staphylococcus aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor.
- CUBICIN®/CUBICIN® RF is **not** indicated for the treatment of pneumonia.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of CUBICIN®/CUBICIN® RF and other antibacterial drugs, CUBICIN®/CUBICIN® RF should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

[II] Skin and soft tissue infections are considered complicated when they involve deeper skin structures, such as fascia or muscle layers, require significant surgical intervention or arise in the presence of significant co-morbidity.

[¥] Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative and/or anaerobic organisms.

[¶] Patients with persisting or relapsing *Staphylococcus aureus* infection or poor clinical response should have repeat blood cultures. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibiotic regimen may be required.

FOR MORE INFORMATION:

Consult the Product Monograph at http://www.sunovion.ca/monographs/cubicin.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use.
The Product Monograph is also available by calling 1-866-260-6291.

1. CUBICIN®/CUBICIN® RF Product Monograph, July 20, 2017.

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NEW Pr Cubicin® RF (daptomycin for injection)

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