Complicated skin and skin structure infections

Eosinophilic pneumonia: Discontinue Daptomycin

Myopathy and rhabdomyolysis

Anaphylaxis/hypersensitivity reactions (including

Indications and Usage (1)

DAPTOMYCIN for injection, for intravenous use

Daptomycin for Injection is a lipopeptide antibacterial agent indicated for treatment of complicated skin and skin structure infections in adults and pediatric patients aged 12 years and older. It is also indicated for the treatment of infections caused by Staphylococcus aureus (methicillin-susceptible and -resistant) and for the treatment of Staphylococcus aureus bacteremia.

Dosage

For complicated skin and skin structure infections, the recommended dosage regimen is 4 mg/kg/day in 1 divided dose. The dose may be adjusted based on the patient's renal function.

Infections caused by S. aureus, the recommended dosage regimen is 4 mg/kg/day in 1 divided dose.

For Staphylococcus aureus bacteremia, the recommended dosage regimen is 4 mg/kg/day in 1 divided dose.

Pediatric use information is approved for Merck & Co., Inc. (Merck).

CONTRAINDICATIONS

Daptomycin for injection is contraindicated in patients with known hypersensitivity to daptomycin.

WARNINGS AND PRECAUTIONS

Anaphylaxis/hypersensitivity reactions: Discontinue Daptomycin for injection immediately and institute appropriate treatment, including epinephrine. Hypersensitivity reactions, including anaphylaxis/hypersensitivity reaction of any type, have been observed with daptomycin for injection. Anaphylaxis/hypersensitivity reactions are potentially fatal and may occur at any time during treatment with daptomycin for injection.

Skin and subcutaneous tissue disorders: In adult patients, skin reactions have included exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, drug reaction with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis. In the pediatric population, skin reactions have included exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions may require hospitalization and may be fatal. If skin reactions occur, discontinue Daptomycin for injection and institute appropriate treatment. These reactions may occur acutely or slowly.

Respiratory system disorders: Eosinophilic pneumonia has been reported with the use of daptomycin for injection. Patients with respiratory symptoms should be treated as clinically indicated, with discontinuation of daptomycin for injection if the symptoms persist.

Cardiovascular system disorders: Myopathy and rhabdomyolysis have been reported with the use of daptomycin for injection. Patients who develop symptoms of myopathy should be treated as clinically indicated, with discontinuation of daptomycin for injection if the symptoms persist.

Psychiatric disorders: Patients who develop symptoms of psychiatric disorders should be treated as clinically indicated, with discontinuation of daptomycin for injection if the symptoms persist.

Gastrointestinal disorders: Patients who develop symptoms of gastrointestinal disorders should be treated as clinically indicated, with discontinuation of daptomycin for injection if the symptoms persist.

Renal function impairment: Daptomycin for injection should be used cautiously in patients with renal function impairment. Reduced dosing may be necessary in patients with severe renal impairment. Patients with impaired renal function should be monitored closely for signs and symptoms of myopathy or rhabdomyolysis.

Drug interactions: Daptomycin for injection has been shown to inhibit the metabolism of several drugs, including warfarin, digoxin, and statins. Monitor patients with renal impairment who are taking concomitant drugs that require metabolism for potential adverse effects.

Incompatibilities: Daptomycin for injection is not compatible with 5% dextrose injection and is compatible with 0.9% sodium chloride injection and lactated Ringer's solution. Daptomycin for injection should not be mixed with blood products or other parenteral solutions.

Drug-Laboratory interaction: The serum sodium concentration may increase during treatment with daptomycin for injection.

Pharmacology: Daptomycin for injection is a lipopeptide antibiotic that inhibits bacterial cell wall synthesis. It has a broad spectrum of activity against Gram-positive bacteria, including S. aureus (methicillin-susceptible and -resistant), and S. pyogenes. Daptomycin for injection has not been evaluated for the treatment of infections caused by non-fermenting Gram-negative bacteria or anaerobes.

Pharmacokinetics: Daptomycin for injection is administered intravenously as a single daily dose. The peak concentration of daptomycin in the serum is reached within 2-4 hours of administration. The half-life of daptomycin is approximately 30 hours in healthy adults. Daptomycin for injection is eliminated primarily by renal excretion, with less than 1% of the dose recovered in the urine as unchanged drug.

Stability: Daptomycin for injection is stable in plasma for at least 24 hours at room temperature and 48 hours when refrigerated. Daptomycin for injection should be stored at room temperature and protected from light.

Investigational studies: Phase II and III clinical trials have evaluated the safety and efficacy of daptomycin for injection in the treatment of complicated skin and skin structure infections, Staphylococcus aureus bacteremia, and Staphylococcus aureus endocarditis. These studies have shown that daptomycin for injection is well tolerated and effective in the treatment of these infections.

REFERENCES


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