Click for Full Prescribing Information including BOXED WARNING, if applicable.

Pfizer Hospital Product Launch
Daptomycin for Injection, 350 mg Single Dose Vial and
Daptomycin for Injection, 500 mg Single Dose Vial

October 4, 2021

Pfizer Hospital is pleased to introduce an additional formulation of our Daptomycin for Injection 350 mg and 500 mg presentations to our portfolio effective immediately. The additional formulation offers important features including:

- **No refrigeration** needed before reconstitution.
- **Storage up to 10 days once reconstituted** with 0.9% sodium chloride, under refrigeration, protected from light.
- **Less time to reconstitute** than original formulation of Daptomycin for Injection.

				Wholesaler Numbers			
Unit of Sale NDC	Unit of Use NDC	Description	Unit of Sale Size	ABC	Cardinal	McKesson	Morris & Dickson
00409-0120-01	00409-0120-01	Daptomycin for Injection, 350 mg Single Dose Vial	1	10260675	5738885	2346468	104729
00409-0122-01	00409-0122-01	Daptomycin for Injection, 500 mg Single Dose Vial	1	10260763	5738893	2346484	104737

Daptomycin for Injection Important Safety Information and Indications

INDICATIONS

Daptomycin for Injection is a lipopeptide antibacterial indicated for the treatment of:

- Complicated skin and skin structure infections (cSSSI) in adult patients.
- *Staphylococcus aureus* bloodstream infections (bacteremia) in adult patients including those with right-sided infective endocarditis.

LIMITATIONS OF USE

- This Daptomycin for Injection product is not approved for use in pediatric patients.
- Daptomycin for Injection is not indicated for the treatment of pneumonia.
- Daptomycin for Injection is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*.
- Daptomycin for Injection 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.

IMPORTANT SAFETY INFORMATION

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

Anaphylaxis/hypersensitivity reactions (including life-threatening): Discontinue Daptomycin for Injection and treat signs/symptoms.

Myopathy and rhabdomyolysis: Monitor CPK levels weekly and follow muscle pain or weakness, particularly in the distal extremities. If elevated CPK or myopathy occurs (defined as muscle aching or muscle weakness with CPK values 5x greater the upper limit of normal (ULN)), consider discontinuing Daptomycin for Injection.

Eosinophilic pneumonia: Can occur 2-4 weeks after starting Daptomycin for Injection. If eosinophilic pneumonia occurs, discontinue Daptomycin for Injection and consider treatment with systemic steroids.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue Daptomycin for Injection and institute appropriate treatment.

Please see important safety information continued below.

PRODUCT BARCODES

Daptomycin for Injection, 350 mg Single Dose Vial **Unit of Sale** 00304090120014	Daptomycin for Injection, 350 mg Single Dose Vial **Unit of Use** 00304090120014
Daptomycin for Injection, 500 mg Single Dose Vial **Unit of Sale** 00304090122018	Daptomycin for Injection, 500 mg Single Dose Vial **Unit of Use** 00304090122018

Please check for product availability via your wholesaler beginning the week of October 4, 2021 (locational inventory may vary). **Direct Orders** will be accepted for the launch product identified in the table above and can be placed for a limited amount of time, beginning today through November 4, 2021 while wholesalers place their initial stocking quantities. To place a **Direct Order**, you can contact Customer Service at 1-844-646-4398 or order via Pfizer Prime (as a reminder, when using Pfizer Prime, the “EA” is the Unit of Sale (UoS) size).

Please contact your Pfizer Hospital sales representative or account executive with any questions.

IMPORTANT SAFETY INFORMATION, CONTINUED

Tubulointerstitial Nephritis (TIN): Discontinue Daptomycin for Injection and follow appropriate treatment.

Peripheral neuropathy: Monitor for neuropathy and consider discontinuing Daptomycin for Injection.

Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months of age: Avoid use of Daptomycin for Injection.

Clostridioides difficile-associated diarrhea: Evaluate patients if diarrhea occurs.

Persisting or relapsing *S. aureus* bacteremia/endocarditis: Perform susceptibility testing and rule out sequestered foci of infection. A change in the antibacterial regimen may be required.

Decreased Efficacy: Adult patients with baseline moderate renal impairment (<50 mL/min) were observed to have decreased efficacy to Daptomycin for Injection.

The most common adverse reactions that occurred in ≥2% of adult cSSSI patients receiving Daptomycin for Injection 4 mg/kg were diarrhea, headache, dizziness, rash, abnormal liver function tests, elevated creatine phosphokinase (CPK), urinary tract infections, hypotension, and dyspnea.

The most common adverse reactions that occurred in ≥5% of *S. aureus* bacteremia/endocarditis patients receiving Daptomycin for Injection 6 mg/kg were sepsis, bacteremia, abdominal pain, chest pain, edema, pharyngolaryngeal pain, pruritus, increased sweating, insomnia, elevated CPK, and hypertension.

Other formulations of Daptomycin for Injection have differences concerning storage and reconstitution. Carefully follow the reconstitution and storage procedures described in the labeling.

Do not use in conjunction with ReadyMED® elastomeric infusion pumps in adult patients.

