Baxter

The First and Only
Frozen Premix

Daptomycin

in 0.9% Sodium Chloride Injection

Adaptobility

4 Manufacturer-Prepared Options to Adapt to Your Workflow

350 mg / 50 mL | 500 mg / 50 mL | 700 mg / 100 mL | 1000 mg / 100 mL

ISMP and ASHP guidelines recommend using commercially prepared, premixed IV products as a risk-reduction strategy for IV medications[1,2]

Safety

30% of hospitals have experienced a patient event involving a compounding error over a 5-year period[3]

- Consistent drug concentrations may minimize medication errors associated with compounding[1,2]
- Barcoded for bedside scanning to help ensure the right patient gets the right medication[1]

Efficiency

Waste of compounded IV medications is significant and hard to monitor[4]

- No admixing or batching required—which may help streamline deployment and save pharmacy time and resources
- Frozen premix medications like Daptomycin support inventory management and help reduce waste[4]
- With four strengths available, premix Daptomycin may help reduce vial waste

Consistent Concentration

- A manufacturer-prepared Daptomycin injection helps ensure that patients receive a consistent concentration of medication

Indications and Select Important Risk Information

Indications: Daptomycin in Sodium Chloride Injection is a lipopeptide antibacterial indicated for the treatment of: Complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age) for whom appropriate dosing can be achieved and, *Staphylococcus aureus* bloodstream infections (bacteremia), in adult patients for whom appropriate dosing can be achieved, including those with right-sided infective endocarditis, *Staphylococcus aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age) for whom appropriate dosing can be achieved.

Limitations of Use: Daptomycin in Sodium Chloride Injection is not indicated for the treatment of pneumonia; **Daptomycin in Sodium Chloride Injection** is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*; **Daptomycin in Sodium Chloride 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.

Contraindications:

- **Daptomycin in Sodium Chloride Injection** is contraindicated in patients with a known hypersensitivity to daptomycin.

Please see full Indications and additional Important Risk Information to follow.

Standardized Manufacturing with Safety in Mind

Manufacturer-prepared IV medications like Daptomycin may help reduce errors associated with compounding.[1,2]

Increase Your Options · Reduce Preparation Steps · Support Patient Care and Pharmacy Efficiency

Adaptable Storage Options for Your Healthcare Facility Needs*

24-month shelf-life when frozen

30 days stability when refrigerated

48 hours stability at room temperature

*Once a frozen product is thawed to refrigeration or room temperature, the product should not be refrozen. Store in a freezer capable of maintaining a temperature of -20°C (-4°F).

When thawed, Daptomycin can be stored and used like any refrigerated medication and has a stability of 30 days.

Baxter offers freezers, refrigerators and thawing systems to fit your pharmacy needs.

Talk to your Baxter representative about how frozen premix Daptomycin adapts to your needs

Select Important Risk Information

Warnings and Precautions

- **Anaphylaxis/Hypersensitivity Reactions:** Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including **daptomycin for injection**, and may be life-threatening. If an allergic reaction occurs, discontinue the drug and institute appropriate therapy.

Dosage and Administration

- If a dose of **Daptomycin in Sodium Chloride Injection** is required that does not equal 350 mg, 500 mg, 700 mg or 1,000 mg, this product is not recommended for use and an alternative formulation of **daptomycin** should be considered.

Please see additional Important Risk Information to follow.

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Frozen Premix: **Daptomycin** in 0.9% Sodium Chloride Injection

Strength	350 mg / 50 mL	500 mg /50 mL	700 mg /100 mL	1,000 mg /100 mL
Product Code	2G3593	2G3594	2G3595	2G3596
NDC	0338-0712-24	0338-0714-24	0338-0716-12	0338-0718-12
UPC	3 03380 71224 3	3 03380 71424 7	3 03380 71612 8	3 03380 71812 2

Daptomycin in 0.9% Sodium Chloride Injection

350 mg/50 mL, 500 mg/50 mL, 700 mg/100 mL, 1,000 mg/100 mL

Indications and Important Risk Information

Indications

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

- Complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age) for whom appropriate dosing can be achieved and,
- *Staphylococcus aureus* bloodstream infections (bacteremia), in adult patients for whom appropriate dosing can be achieved, including those with right-sided infective endocarditis,
- *Staphylococcus aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age) for whom appropriate dosing can be achieved.

Limitations of Use:

- **Daptomycin in Sodium Chloride Injection** is not indicated for the treatment of pneumonia.
- **Daptomycin in Sodium Chloride Injection** is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*.
- **Daptomycin in Sodium Chloride 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.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of **Daptomycin in Sodium Chloride Injection** and other antibacterial drugs, **Daptomycin in Sodium Chloride Injection** should be used to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Please see Important Risk Information continued on following page.

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Daptomycin in 0.9% Sodium Chloride Injection

Important Risk Information

Contraindications

- **Daptomycin in Sodium Chloride Injection** is contraindicated in patients with a known hypersensitivity to daptomycin.

Warnings and Precautions

- **Anaphylaxis/Hypersensitivity Reactions:** Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including **daptomycin for injection**, and may be life-threatening. If an allergic reaction occurs, discontinue the drug and institute appropriate therapy.
- **Myopathy and Rhabdomyolysis:** Patients receiving **Daptomycin in Sodium Chloride Injection** should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. CPK levels should be monitored weekly, and more frequently in patients who received recent, prior, or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment.
  In adult patients with renal impairment, both renal function and CPK should be monitored more frequently than once weekly. **Daptomycin in Sodium Chloride Injection** should not be dosed more frequently than once a day.
  Daptomycin in Sodium Chloride Injection should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels >1,000 U/L, and in patients without reported symptoms who have marked elevations in CPK, with levels >2,000 U/L.
- **Eosinophilic Pneumonia:** Has been reported in patients receiving **daptomycin for injection**. In reported cases, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates or organizing pneumonia. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting **daptomycin for injection** and improved when discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms should undergo prompt medical evaluation, and **Daptomycin in Sodium Chloride Injection** should be discontinued immediately.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** DRESS has been reported in post-marketing experience. Patients who develop skin rash, fever, peripheral eosinophilia, and systemic organ (for example, hepatic, renal, pulmonary) impairment while receiving **Daptomycin in Sodium Chloride Injection** should undergo medical evaluation. If DRESS is suspected, discontinue promptly and institute appropriate treatment.
- **Tubulointerstitial Nephritis (TIN):** TIN has been reported in post-marketing experience. Patients who develop new or worsening renal impairment while receiving **Daptomycin in Sodium Chloride Injection** should undergo medical evaluation. If TIN is suspected, discontinue promptly and institute appropriate treatment.
- **Peripheral Neuropathy:** Cases have been reported during post-marketing experience. Therefore, physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving **Daptomycin in Sodium Chloride Injection**. Monitor for neuropathy and consider discontinuation.
- **Potential Nervous System and/or Muscular System Effects in Pediatric Patients Younger than 12 Months:** Avoid use in pediatric patients younger than 12 months due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs with intravenous **daptomycin**.
- ***Clostridioides difficile*-Associated Diarrhea (CDAD):** CDAD has been reported with the use of nearly all systemic antibacterial agents, including **daptomycin for injection**, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.
- **Persisting or Relapsing *S. aureus* Bacteremia/Endocarditis:** Patients should have repeat blood cultures. If a blood culture is positive for *S. aureus*, minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention and/or consideration of a change in antibacterial regimen may be required. Failure of treatment may be due to reduced **daptomycin** susceptibility.
- **Decreased efficacy was observed in adult patients with moderate baseline renal impairment:** Consider these data when selecting antibacterial therapy for use in adult patients with baseline moderate to severe renal impairment.

Please see additional Important Risk Information continued on following page.

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Daptomycin in 0.9% Sodium Chloride Injection

Important Risk Information, cont.

- **Adverse Reactions:**
  - o Adult cSSSI Patients: 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.
  - o Pediatric cSSSI Patients: The most common adverse reactions that occurred in ≥2% of pediatric patients receiving **daptomycin for injection** were diarrhea, vomiting, abdominal pain, pruritus, pyrexia, elevated CPK, and headache.
  - o Adult *S. aureus* bacteremia/endocarditis Patients: 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.
  - o Pediatric *S. aureus* bacteremia Patients: The most common adverse reactions that occurred in ≥5% of pediatric patients receiving **daptomycin for injection** were vomiting and elevated CPK.
- **Drug Interactions:**
  - o **HMG-CoA Reductase Inhibitors:** Inhibitors of HMG-CoA reductase may cause myopathy. Experience with the coadministration of HMG-CoA reductase inhibitors and **daptomycin for injection** in patients is limited; therefore, consideration should be given to suspending use of HMG-CoA reductase inhibitors temporarily in patients receiving **Daptomycin in Sodium Chloride Injection**.
  - o **Drug-Lab Test Interactions: Increased International Normalized Ratio (INR)/Prolonged Prothrombin Time:** Clinically relevant plasma concentrations of **daptomycin** have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay.

Dosage and Administration

- If a dose of **Daptomycin in Sodium Chloride Injection** is required that does not equal 350 mg, 500 mg, 700 mg or 1,000 mg, this product is not recommended for use and an alternative formulation of **daptomycin** should be considered.

Please see accompanying full Prescribing Information for Daptomycin in 0.9% Sodium Chloride Injection.

References: 1. Institute for Safe Medication Practices. ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology; 2022. https://www.ismp.org/resources/guidelines-sterile-compounding-and-safe-use-sterile-compounding-technology. Accessed May 15, 2023. **2.** Billstein-Leber M, Carrillo JD, Cassano AT, et al. ASHP Guidelines on Preventing Medication Errors in Hospitals. *Am J Health-Syst Pharm*. 2018;75:1493-1517. DOI 10.2146/ajhp170811. **3.** Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations; 2016. https://www.ismp.org/guidelines/sterile-compounding. Accessed May 12, 2023. **4.** ASHP Expert Panel on Medication Cost Management. ASHP guidelines on medication cost management strategies for hospitals and health systems. *Am J Health-Syst Pharm*. 2008;65(14):1368-1384.

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US-PH109-230003 V 1.0 6/2023

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