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### Table 1: Recommended Dose of Daptomycin for Injection Adults

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus Bloodstream Infections</td>
<td>4 mg/kg once every 24 hours</td>
</tr>
<tr>
<td>S. aureus Endocarditis</td>
<td>4 mg/kg once every 24 hours</td>
</tr>
</tbody>
</table>

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### Table 2: Global Success Rates by Daptomycin and Treatment Group in Phase 3 INDUC-1A Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Daptomycin</th>
<th>Comparator</th>
<th>Success Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUC-1A</td>
<td>82.4</td>
<td>72.2</td>
<td>10.2</td>
</tr>
</tbody>
</table>

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## CLINICAL PHARMACOLOGY

1. **Bactericidal Mechanism**: Daptomycin acts by inhibiting the assembly of bacterial membranes, leading to cell lysis. It is active against a wide range of Gram-positive bacteria, including methicillin-resistant S. aureus (MRSA) and vancomycin-resistant enterococci (VRE).

2. **Pharmacokinetics**: Daptomycin is administered via intravenous infusion. It achieves high concentrations in plasma and tissues, with rapid distribution into cells. It is excreted unchanged in the urine and bile.

3. **Duration**: Treatment is typically for 7 to 14 days, depending on the infection site and severity.

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## DOSAGE AND ADMINISTRATION

1. **Daptomycin for Injection**: For intravenous use. Reconstitute the vial with 3 mL of sterile water for injection, USP, to yield a concentration of 10 mg/mL. Mix gently until completely dissolved. Administer the solution over a period of 30 minutes. DO NOT dilute or administer with other medicines through the same line.

2. **Dosages**:
   - For S. aureus bloodstream infections: 4 mg/kg once every 24 hours for 7 to 10 days.
   - For S. aureus endocarditis: 4 mg/kg once every 24 hours for 7 to 10 days.

3. **Adjustments**:
   - Patients with impaired renal function: Decreased doses or delayed administration may be necessary in patients with moderate to severe impairment.
   - Patients with impaired hepatic function: No dose adjustment is required.

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## CONTRAINDICATIONS

1. **Hypersensitivity to Daptomycin**: Patients with a history of allergy to daptomycin should not receive the drug.

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## PRECAUTIONS

1. **Overgrowth of Anaerobic Bacteria**: The use of Daptomycin for Injection is associated with a risk of overgrowth of anaerobic bacteria, particularly in patients with bacteremia or endocarditis.

2. **Diluted Solution Stability**: The diluted solution is stable in the infusion bag for 12 hours at room temperature and 48 hours if stored at 2° to 8°C (36° to 46°F).

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## ADVERSE REACTIONS

1. **Peripheral Neuropathy**: Peripheral neuropathy has been reported in patients receiving Daptomycin for Injection. It is characterized by muscle weakness, loss of sensation, and/or sensory changes.

2. **Myopathy and Rhabdomyolysis**: These adverse effects can include muscle pain, weakness, and CPK elevations.

3. **Eosinophilic Pneumonia**: Eosinophilic pneumonia has been reported in patients receiving daptomycin for injection.

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## DRUG INTERACTIONS

1. **Cimetidine**: Cimetidine is a strong CYP3A4 inhibitor. Co-administration of cimetidine with Daptomycin for Injection may result in increased daptomycin concentrations, potentially leading to increased toxicity.

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## DAPTOMYCIN RESISTANCE

1. **Mechanisms**: Resistance to daptomycin can develop through modifications in the bacterial cell wall or changes in membrane permeability.

2. **Clinical Significance**: Resistance is associated with a decreased likelihood of clinical success.

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## PATIENT INFORMATION

1. **Explanation of Medication**: Explain to patients the purpose of Daptomycin for Injection and the importance of completing the full course of treatment.

2. **Side Effects**: Inform patients about potential side effects, including peripheral neuropathy and myopathy.

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## ACKNOWLEDGMENT

This information is based on data from various sources, including clinical trials and expert opinions. For the most current and comprehensive information, consult the manufacturer's package insert and relevant medical literature.
Of the 534 adult patients treated with daptomycin for injection in Phase 3 controlled clinical trials of 12.3 Pharmacokinetics

Table 7: Mean (SD) Daptomycin Pharmacokinetic Parameters in HN

Note: Daptomycin for injection was administered over a 30-minute period.

Table 8: Mean (SD) Daptomycin Pharmacokinetic Parameters Following Administration of a Single Dose Injection or IV Infusion in Subjects with Various Degrees of Renal Function

Table 9: Mean (SD) Daptomycin Pharmacokinetic Parameters Following a Multiple Dose IV Infusion in Subjects with Various Degrees of Renal Function

Table 10: Clinical Success Rates by Dosing Regimens in the EUP Trial in Adult Patients (Daptomycin for Injection)

Table 11: Pharmacodynamic Parameters for Daptomycin in the EUP Trial

Table 12: Clinical Success Rates by Dosing Regimens in the EUP Trial in Adult Patients (Daptomycin for Injection)