Amphotericin B FOR INJECTION, USP

PRODUCT SUMMARY

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<th>10 DIGIT</th>
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<td>39822-1055-5</td>
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WHOLESALE NUMBERS

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<td>ABC</td>
<td>10047074</td>
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<td>CARDINAL</td>
<td>1199140</td>
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<td>McKesson</td>
<td>1670776</td>
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<tr>
<td>Morris Dickson</td>
<td>370049</td>
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STORAGE INFORMATION

Refrigerated Storage Required
2° to 8°C (36° to 46°F)

FULL PRESCRIBING INFORMATION

INJECTABLE PRODUCT

PRESERVATIVE FREE
LATEX FREE STOPPER
BARCODED FOR PATIENT SAFETY

OTHER INFORMATION

YOUR TRUSTED CHOICE
FOR GENERIC PHARMACEUTICALS
www.x-gen.us • 866-390-4411
Amphotericin B for Injection, USP

Amphotericin B for Injection, USP is available in a single dose powder for dilution in sterile water for injection or 5% dextrose injection. To avoid confusion, it is recommended to use sterile water for injection for dilution. The labeled strength is 5 mg/mL. When diluted with sterile water for injection, this vial yields an injectable solution containing 5 mg/mL amphotericin B, 2 mg/mL benzyl alcohol, and 20 mg/mL of sodium acetate. Commercially, this solution should be prepared and used within 24 hours. Concentrations in excess of 5 mg/mL are not recommended because of the risk of intravenous precipitation.

Each vial contains a sterile, nonpyrogenic, lyophilized cake (which may partially reduce to powder following manufacture) containing amphotericin B (1 mg amphotericin B/3 mL injection solution) and sterile water for injection (2 mL per vial). Commercially, Amphotericin B for Injection should be reconstituted by adding 2 mL of sterile water for injection to provide a final concentration of 5 mg/mL. The reconstituted solution is stable for 24 hours at room temperature or for 7 days if refrigerated. The solution should be examined visually for particulate matter and discoloration prior to administration. Any degradation of the solution is a reason to discard it.

Each vial of Amphotericin B for Injection contains 1 mg of amphotericin B (2 mg/mL in 3 mL injection solution) and sterile water for injection (2 mL per vial). Commercially, Amphotericin B for Injection should be reconstituted by adding 2 mL of sterile water for injection to provide a final concentration of 5 mg/mL. The reconstituted solution is stable for 24 hours at room temperature or for 7 days if refrigerated. The solution should be examined visually for particulate matter and discoloration prior to administration. Any degradation of the solution is a reason to discard it.

CAUTION: Under no circumstances should a total daily dose of 1.5 mg/kg be exceeded. Amphotericin B for Injection should not be given at doses greater than 1.5 mg/kg.

Amphotericin B for Injection should be injected slowly over a 1 to 3 hour period. Each vial contains 10 mg amphotericin B, which will yield a 2 mg/mL injection solution when reconstituted according to the directions above. The total daily dose should not exceed 1.5 mg/kg. Amphotericin B contains 2 mg/mL benzyl alcohol, which should be considered in patients with known benzyl alcohol sensitivity.

Amphotericin B for Injection is distributed by Bristol-Myers Squibb Company, 2200 University Avenue, West Haven, Connecticut 06516.

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