

FIRST TIME GENERIC APPROVAL

Brand Name	AmBisome®
Generic Name	amphotericin b
Drug Manufacturer	Sun Pharmaceutical Industries, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

December 14, 2021

LAUNCH DATE

February 9, 2022

REVIEW DESIGNATION

Abbreviated New Drug Application (ANDA): 212514

TYPE OF REVIEW

Standard

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Amphotericin B liposome for injection is indicated for the following:

- Empirical therapy for presumed fungal infection in febrile, neutropenic patients.
- Treatment of Cryptococcal Meningitis in HIV infected patients.
- Treatment of patients with Aspergillus species, Candida species and/or Cryptococcus species infections (see above for the treatment of Cryptococcal Meningitis) refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate.
- Treatment of visceral leishmaniasis. In immunocompromised patients with visceral leishmaniasis treated with amphotericin B liposome for injection, relapse rates were high following initial clearance of parasites.

MECHANISMS OF ACTION

Amphotericin B, the active ingredient of amphotericin B liposome for injection, acts by binding to the sterol component, ergosterol, of the cell membrane of susceptible fungi. It forms transmembrane channels leading to alterations in cell permeability through which monovalent ions (Na⁺, K⁺, H⁺, and Cl⁻) leak out of the cell resulting in cell death. While amphotericin B has a higher affinity for the ergosterol component of the fungal cell membrane, it can also bind to the cholesterol component of the mammalian cell leading to cytotoxicity.

Amphotericin B liposome for injection, the liposomal preparation of amphotericin B, has been shown to penetrate the cell wall of both extracellular and intracellular forms of susceptible fungi.

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DOSE FORM AND STRENGTH

50 MG/VIAL

DOSE & ADMINISTRATION

The recommended initial dose of amphotericin B liposome for injection for each indication for adult and pediatric patients is as follows:

Indication	Dose (mg/kg/day)
Empirical therapy	3
Systemic fungal infections: <i>Aspergillus</i> <i>Candida</i> <i>Cryptococcus</i>	3 to 5
Cryptococcal meningitis in HIV infected patients	6

Dosing and rate of infusion should be individualized to the needs of the specific patient to ensure maximum efficacy while minimizing systemic toxicities or adverse events.

Doses recommended for visceral leishmaniasis are presented below:

Visceral Leishmaniasis	Dose (mg/kg/day)
Immunocompetent patients	3 (days 1 to 5) and 3 on days 14, 21
Immunocompromised patients	4 (days 1 to 5) and 4 on days 10, 17, 24, 31, 38

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