

Response from Gilead 31 August

AmBisome® (amphotericin B) liposome for injection was originally developed and commercialized by NeXstar Pharmaceuticals. Gilead acquired NeXstar in 1999, bringing AmBisome into Gilead's portfolio. As the foundational patents covering the formulation have expired, no licensing is required to enable generic manufacturing.

Generic liposomal amphotericin B products have been developed and are available in several markets, including South Africa, the United States, Australia and the United Kingdom. Where no other equivalent treatment options are available, Gilead operates a global access program under which AmBisome is made available at a no-profit price to governments and qualifying non-governmental health organizations serving public-sector programs in low- and middle-income countries for visceral leishmaniasis and cryptococcal meningitis. In markets where generic versions are available, Gilead does not offer a separate access price or pathway for AmBisome.

Separately, Gilead has a long-standing partnership with the World Health Organization focused on eliminating visceral leishmaniasis. In 2026, Gilead extended that partnership through 2030 and donated more than 400,000 vials of AmBisome and provided \$9.2 million in financial support. The program supports countries representing approximately 74% of the global visceral leishmaniasis burden.

Gilead continues to evaluate how best to support sustainable access to AmBisome where no generic option is available, including through its no-profit public-sector access program, its partnership with WHO and investments in manufacturing capacity.