

FDA authorizes foreign importation of Bicillin® L-A (penicillin G benzathine)

- Pfizer’s [Bicillin L-A \(penicillin G benzathine\)](#) injection has been a shortage since [April 2023](#) due to increased demand. To bolster supply, the FDA is coordinating with Laboratories Delbert in conjunction with Provepharm and Direct Success to [temporarily import](#) their penicillin G benzathine product, Extencilline (benzathine benzylpenicillin), into the U.S. This product is not a FDA-approved product but is being given special authorization due to the shortage.
- Per [Pfizer](#), there is limited supply of Bicillin L-A of the 1.2 million units/2mL and 2.4 million units/2mL strengths. The pediatric 600,000 unit/mL strength is not available. Pfizer estimates that supply will recover by the 2nd quarter of 2024.
- Bicillin L-A is indicated in the treatment of infections due to penicillin-G-sensitive microorganisms. Infections that usually respond to intramuscular penicillin G benzathine include mild-to-moderate infection of the upper respiratory tract due to susceptible streptococci and venereal infections (e.g., syphilis).
- Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of rheumatic fever and/or chorea. It has also been used as follow-up prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.
- At this time, no other entity except Provepharm or its distributor Direct Success is authorized by the FDA to import or distribute Extencilline in the U.S.
- Effective immediately, Provepharm will distribute the following presentations of Extencilline:

Product Description	Strength	Packaging	NDC #	Lot #	Expiration Date
Extencilline (benzathine benzylpenicillin) powder and diluent for reconstitution for injection	1,200,000 units	20 mL vials of powder for suspension	81284-521-01	72L00127	10/31/2025
	2,400,000 units	5 mL of water for injection in ampules	81284-522-01	72L00122	

- Refer to the [notice](#) for information on key differences between the U.S. marketed Bicillin L-A and Extencilline.