

Availability of Extencilline as an Alternative Treatment Option for Syphilis

FEBRUARY 1, 2024

The Centers for Disease Control and Prevention (CDC) has informed partners ([FDA Announcement on Availability of Extencilline \(cdc.gov\): https://www.cdc.gov/std/dstdp/dcl/2024-january-16-availability-of-extencilline.htm](https://www.cdc.gov/std/dstdp/dcl/2024-january-16-availability-of-extencilline.htm)) that the Food and Drug Administration (FDA) is temporarily allowing the importation of an antibiotic named Extencilline (benzathine benzylpenicillin) that can be used to treat syphilis during the ongoing shortage of Bicillin L-A (penicillin G benzathine benzylpenicillin). Extencilline is not FDA-approved but has been determined to be **equivalent to Bicillin L-A** and is authorized for use in other countries (including in France). **MDH supports use of this alternative when Bicillin L-A is unavailable.**

Effective immediately, Provepharm will distribute the following presentations of Extencilline powder and diluent for reconstitution and injection:

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

IMPORTANT: Providers should be aware of the following key similarities and differences between Extencilline and U.S. marketed Bicillin L-A:

Similarities:

- Both drugs are penicillins. Therefore, before initiating therapy with benzylpenicillin benzathine, a careful investigation should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents.
- Similar to Bicillin L-A, the Extencilline preparation is strictly for intramuscular injection.

Differences:

- Extencilline contains soy phospholipids and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in patients with a history of allergy to soybeans
- Extencilline is supplied as powder for reconstitution, compared to a pre-filled disposable syringe for Bicillin L-A:
 - Follow instructions for the preparation of an intramuscular injection of Extencilline as detailed in the Preparation section of the [Healthcare Provider Letter](#).
- The volume of Extencilline after reconstitution is higher than Bicillin L-A. Providers should adjust their protocols for intramuscular injection to account for this higher volume, following instructions in the preparation section of the health care provider letter, including the option of reconstituting with injectable lidocaine solution.

Extencilline 1,200,000 units	5mL volume after reconstitution for intramuscular injection	compared to	Bicillin L-A 1,200,000 units	2mL
Extencilline 2,400,000 units	7mL volume after reconstitution for intramuscular injection	compared to	Bicillin L-A 2,400,000 units	4mL

- Unlike Bicillin L-A prefilled syringes, Extencilline powder does not require refrigeration or other special storage conditions. However, once reconstituted, Extencilline should be used immediately.
- There are several labeling differences between Extencilline and Bicillin L-A:
 - Extencilline labeling does not contain a boxed warning. Providers should refer to the Bicillin L-A boxed warning (which contains a warning that the product is not for intravenous use).
 - Extencilline carton labeling does not have the warning “Fatal if given by other routes”.
 - Extencilline labeling does not include detailed instructions for deep intramuscular administration.
 - Extencilline does not have the statement “Rx only” on the labeling (although will be available only by prescription in the U.S.)
- For further details, including indications for usage of benzylpenicillin benzathine during pregnancy and breastfeeding, see the healthcare provider letter linked above.

Availability

To place an order for Extencilline, providers should contact Direct Success at Distribution@dsuccess.com or call 1-877-404-3338. For additional information related to the product, please contact Provepharm, the U.S. distribution partner, at medicalaffairs@provepharm.com or 610-601-8600. Note that at this time, 340b funding cannot be used for purchasing Extencilline.

Barcode

The barcode on the imported product label may not register accurately on U.S. scanning systems. Sites should manually input the correct product information into their systems and follow alternative procedures to assure the correct drug product is being used and administered to patients.

References

For questions on syphilis screening, diagnosis, or treatment, call the Minnesota Department of Health at (651) 201-5414.

- [CDC: FDA Announcement on Availability of Extencelline \(https://www.cdc.gov/nchhstp/dear_colleague/2024/dcl-01122024-fda-bicillin.html\)](https://www.cdc.gov/nchhstp/dear_colleague/2024/dcl-01122024-fda-bicillin.html).
- [FDA: Letter to Healthcare Providers on Temporary Importation of Extencelline \(https://www.fda.gov/media/175366/download\)](https://www.fda.gov/media/175366/download)
- [CDC Sexually Transmitted Infections Guidelines 2021: Syphilis \(https://www.cdc.gov/std/treatment-guidelines/syphilis.htm\)](https://www.cdc.gov/std/treatment-guidelines/syphilis.htm)