

Extencilline (benzathine benzylpenicillin)

What is Extencilline?

Extencilline is benzathine benzylpenicillin (penicillin G benzathine) injection powder for suspension that is being temporarily imported to address <u>ongoing shortages of Bicillin[®] L-A</u> (penicillin G benzathine injectable suspension) in the United States.

In what form is Extencilline available?

Extencilline (benzathine benzylpenicillin) is a powder and diluent for reconstitution for injection of 1,200,000 units and 2,400,000 units.

What are the key differences between Bicillin® L-A and Extencilline?

	Bicillin [®] L-A	Extencilline	
Active Ingredients	penicillin G benzathine in aqueous suspension with sodium citrate buffer	benzathine benzylpenicillin coated with lecithin and polysorbate	
Additional Ingredients	sodium citrate, povidone, carboxymethylcellulose sodium, lecithin, methylparaben, and propylparaben	carmellose sodium, anhydrous sodium citrate, and povidone * Contains soy phospholipids which may cause hypersensitivity reactions (urticaria, anaphylactic shock) in people with a history of allergy to soybeans	
Dosage form	prefilled disposable syringes, injectable suspension	powder and diluent for reconstitution, injection powder for suspension	
Diluent	not applicable	4 mL of sterile water for injection for 1,200,000 unit dose 5 mL of sterile water for injection for 2,400,000 unit dose The same volume (4 mL or 5 mL, respectively) of 1% or 0.5% lidocaine injectable solution may also be used as the diluent instead of water.	
Volume of administration	2 mL for 1,200,000 unit dose per syringe 4 mL for 2,400,000 unit dose per syringe	5 mL for 1,200,000 unit dose after reconstitution 7 mL for 2,400,000 unit dose after reconstitution	
Storage	Store in a refrigerator, 2° to 8°C (36° to 46°F). Keep from freezing.	Vial of Extencilline powder does not require any special storage condition. It does not need to be refrigerated. Following reconstitution, Extencilline should be used immediately. It should not be stored for later use.	

* The barcode on the imported product label may not register accurately on the U.S. scanning systems. Institutions should manually input the imported product information into their systems and confirm that the barcode, if scanned, provides correct information.

To place an Extencilline order:

Distribution@dsuccess.com or 1-877-404-3338

To report adverse reactions related to Extencilline:

safety-us@provepharm.com or 1-833-727-6556

For additional information related to Extencilline:

medicalaffairs@provepharm.com or 1-610-601-8600

To report Bicillin® L-A shortages: stdshortages@cdc.gov

Additional resources about Extencilline:

- Healthcare Provider Letter
- CDC STI Treatment Guidelines
- <u>STD Clinical Consultation Network</u>

Extencilline Preparation and Administration Guide

Preparation:

Extencilline is supplied as 1 vial and 1 glass ampule of diluent for reconstitution.

Instructions for the preparation of an intramuscular injection of a dose of 1,200,000 units:

The suspension must be prepared aseptically.

- With a graduated syringe for intramuscular injection (needle gauge: 22, 21, or 20), take 4 mL of sterile water for injection from the ampule of diluent contained in the box. Note that the ampule of diluent provided in the box contains 5 mL of sterile water for injection; only 4 mL of diluent is needed for the preparation of this 1,200,000 unit suspension. 4 mL of 1% or 0.5% lidocaine injectable solution may also be used as the diluent instead of water.
- 2. Into the vial of powder of 1,200,000 units, add the 4 mL of sterile water for injection taken from the ampule of diluent, or add the 4 mL of 1% or 0.5% lidocaine injectable solution.
- 3. Gently shake this suspension for at least 20 seconds until a homogenous suspension is obtained. Withdraw the entire contents of the vial into the syringe to equal the total labeled dose. Use the suspension immediately as soon as it is prepared.
- 4. After reconstitution with 4 mL of diluent, each 5 mL suspension will contain approximately 1,200,000 units of benzathine benzylpenicillin.

For doses of Extencilline less than 1,200,000 units: withdraw the appropriate volume of the reconstituted product and discard the remainder. For example, to obtain a dose of 600,000 units of Extencilline, withdraw half the volume of the reconstituted 1,200,000 unit product, then discard the remainder.

When preparing an intramuscular injection of a dose of 2,400,000 units: follow the identical instructions as with 1,200,000 units but use 5 mL of diluent (water or lidocaine). After reconstitution with 5 mL of diluent, each 7 mL suspension will contain approximately 2,400,000 units. This reconstitution must be given as two separate injections of 3.5 mL each.

Vial Dosage	Amount of Diluent to Be Added	Final Concentration
1,200,000 units	4 mL	1,200,000 units per 5 mL suspension
2,400,000 units	5 mL	2,400,000 units per 7 mL suspension

Administration:

The preparation is strictly for deep intramuscular injection only. Administration is similar to Bicillin® L-A.

- Inspect visually for particulate matter and discoloration prior to administration.
- Do not inject intravenously or mix with other intravenous solutions since this has been associated with cardiorespiratory arrest and death.
- Administer into the upper, outer quadrant of the buttock (dorsogluteal) or the ventrogluteal site; in neonates, infants, and small children it may be preferable to administer in the midlateral aspect of the thigh.
- Do not inject into or near an artery or nerve. Do not inject into the anterolateral thigh as quadriceps femoris fibrosis and atrophy have been reported. **Do not inject into the arm.**
- Due to the high concentration of suspended material in this product, to avoid blockage of the needle, administer at a slow, steady rate.
- When doses are repeated, vary the injection site.
- If any discoloration appears upon insertion of the needle and aspiration, withdraw the needle and discard.