Lentocilin© Information for Clinicians

Lentocilin© (benzathine benzylpenicillin)

What is Lentocilin©?

Lentocilin© is benzathine benzylpenicillin tetrahydrate (penicillin G benzathine) injection powder for suspension that is being temporarily imported to address shortages of Bicillin® L-A (penicillin G benzathine injectable suspension) in the United States.

In what form is Lentocilin© available?

Lentocilin© (benzathine benzylpenicillin tetrahydrate) is a powder and diluent for reconstitution for injection of 1,200,000 units.

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

	Bicillin® L-A	**Lentocilin©**
Warnings	Bicillin® L-A has a boxed warning. Bicillin® L-A carton labeling states that it is, "Fatal if given by other routes."	Lentocilin© does not have a boxed warning. Please refer to the Bicillin® L-A boxed warning. While not on the carton labeling, the product information states that Lentocilin© "must be administered EXCLUSIVELY by DEEP INTRAMUSCULAR (IM) injection."
Soy Phospholipids	Bicillin® L-A does not contain soy phospholipids.	Lentocilin© contains soy phospholipids and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in people with a history of allergy to soybeans.
Lidocaine	Bicillin® L-A does not contain lidocaine.	Lentocilin© contains lidocaine and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in people with a history of allergy to lidocaine or local anesthetics of the amide type. It should be used with caution in patients with cardiovascular, hepatic or renal disease.
Additional Ingredients	Sodium citrate, povidone, carboxymethylcellulose sodium, lecithin, methylparaben, and propylparaben	Soybean lecithin, polysorbate 80, water, lidocaine hydrochloride, and monosodium citrate
Dosage form	Prefilled disposable syringes, injectable suspension	Powder and diluent for reconstitution

Diluent	Not applicable	4 ml of 1.5% lidocaine hydrochloride solution contained in a glass ampule
Volume of administration	2 mL for 1,200,000 unit	4 mL for 1,200,000 unit dose after reconstitution
Storage	Store in a refrigerator, 2° to 8°C (36° to 46°F). Keep from freezing.	Store below 25°C (77°F). Store in the original package to prevent light and moisture. **Following reconstitution, use immediately.**

How do I get Lentocilin©?

Please refer to information from the U.S. Food and Drug Administration Information.

Additional resources about Lentocilin© are as follows:

- Lentocilin© Package Insert
- FDA Healthcare Provider Letter
- CDC STI Treatment Guidelines
- STD Clinical Consultation Network

* **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.

Lentocilin© Preparation and Administration Guide

Preparation:

Lentocilin© is supplied as 1 vial of powder 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.

1. Draw up 4 mL diluent into a needle per standard medication administration procedures.
2. Disinfect the rubber stopper of the vial with alcohol and insert the needle through its center. Without touching the powder, carefully inject the diluent into the vial. Do not inject the diluent directly into the powder. Remove the needle from the vial.
3. Homogenize the suspension by rotating the vial tightly between the hands for about 20 seconds. Do not shake.
4. Transfer the suspension immediately into a syringe and proceed to administer as soon as possible.

After reconstitution the 4 mL suspension will contain approximately 1,200,000 units of benzathine benzylpenicillin.

For doses of Lentocilin© less than 1,200,000 units: withdraw the appropriate volume of the reconstituted product and discard the remainder.

Administration:

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

- Use a needle in the administration with a minimum internal diameter of 0.8mm (caliber: 18 gauge).
- Inspect the syringe visually for particulate matter and discoloration prior to administration. If any discoloration appears upon insertion of the needle and aspiration, withdraw the needle and discard.
- 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. If the needle is clogged, replace it with a new needle.
- When doses are repeated, vary the injection site.