



Health Alert: Penicillin G Benzathine (Bicillin L-A) Voluntary Recall and Shortage

July 15, 2025

Situational Update: Bicillin L-A Recall

On July 10, 2025, Pfizer, the manufacturer of penicillin G benzathine (Bicillin L-A), issued a <u>voluntary recall</u> of affected product lots due to particulates identified in the syringes during visual inspection. This includes both 1.2 million units/2 mL and 2.4 million units/4 mL prefilled syringes distributed from **December 11, 2023 – June 24, 2025**.

Please **check your Bicillin stock immediately** as affected <u>lots</u> (see below) should be discontinued. You can find more information about credit reimbursement for returned affected lots in Pfizer's Bicillin L-A <u>recall notification</u>.

In response to this recall and as Pfizer is the only manufacturer of Bicillin L-A, the <u>FDA</u> anticipates a limited supply of Bicillin L-A 1.2 and 2.4 mu doses *with no estimated recovery date*.

Bicillin L-A is the <u>only</u> acceptable treatment for pregnant people infected with or exposed to syphilis and should be prioritized for babies exposed to syphilis in utero. Utilizing <u>Pfizer's Medical Request Process</u>, providers and pharmacy directors who no longer have wholesale or hospital system access to Bicillin L-A can submit a <u>medical request form</u> for patients who can only receive Bicillin L-A due to the risk of congenital syphilis.

Among non-pregnant adults, doxycycline 100 mg PO BID x 14 days is an acceptable alternative for those with primary, secondary, or early latent syphilis, and for those who have been exposed to a patient with infectious syphilis. Doxycycline 100 mg PO BID x 28 days is an acceptable alternative for those with late latent syphilis. Limited data support ceftriaxone as an effective therapy option for the treatment of primary and secondary syphilis, and neurosyphilis, in non-pregnant adults. Extencilline and Lentocilin were approved by FDA for temporary importation due to prior shortages and remain available.

Other intramuscular formulations of penicillin (e.g. Bicillin C-R) are *not* acceptable alternatives for the treatment of syphilis.





Actions Requested of SF Clinicians

- **1.** Check your clinic's Bicillin L-A stock against the list of affected lots and discontinue using any affected lots immediately.
- 2. Prioritize penicillin G benzathine (Bicillin L-A) for pregnant people and infants with syphilis infection or exposure, and those with an allergy to doxycycline.
- 3. Use doxycycline to treat non-pregnant adults with primary, secondary, early latent or late latent syphilis, or who are contacts to syphilis, who are able to adhere to a multi-day regimen.
- **4. Use alternative drugs** to treat group A strep pharyngitis and for primary rheumatic fever prophylaxis, e.g. penicillin V, amoxicillin, and azithromycin to conserve Bicillin L-A.
- 5. Contact SF City Clinic at (628) 217-6677 if you are having trouble obtaining Bicillin L-A.

Additional Resources: Bicilin L-A

• <u>Pfizer announces urgent recall of Bicillin L-A</u>, affected lot numbers below

Carton NDC	Syringe NDC	Lot Number	Expiration Date YYMMDD	Strength	Configuration/ Count
60793-701-10	60793-701-02	GL2954	270131	1,200,000 units/ 2 mL	10 (2 mL) syringes per carton, 24 cartons per shipping case
		HP6222	270131		
		HP6228	271031		
		HP6232	270930		
		HR9967	270531		
		HJ3235	260930		
		LT5190	270930		
60793-702-10	60793-702-04	GT2598	260930	2,400,000 units/ 4 mL	10 (4 mL) syringes per carton, 24 cartons per shipping case
		GT2599	260930		
		HR9969	270430		
		НК2909	270228		
		HR9984	270831		

- Pfizer Bicillin Supply Update July 2025
- FDA on Bicillin L-A shortage and availability of Extencilline
- Extencilline Ordering and Administration Instructions
- CDC STI Treatment Guidelines for Syphilis
- <u>CDPH: Alternative therapies for the treatment of syphilis in non-pregnant adults</u>

Program Contact Information

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