## Recall of Long-Acting Penicillin G Benzathine Injectable Suspension Products (Bicillin L-A®)

- Specific lots of long-acting penicillin G benzathine injectable suspension products (Bicillin L-A) have been recalled due to particulates in the products.
- Providers should check their Bicillin L-A inventory and immediately stop the use and distribution of any affected products.
- If Bicillin L-A inventory is low, providers should reserve doses for pregnant people with or exposed to syphilis, infants with syphilis, and people with syphilis who are unable to take doxycycline.

July 30, 2025

## Dear Colleagues,

On July 10, 2025, King Pharmaceuticals LLC., a subsidy of Pfizer, announced a voluntary recall of identified lots of long-acting penicillin G benzathine injectable suspension products (Bicillin L-A) due to particulates identified during visual inspection. Providers must immediately check their stock against the referenced product lots listed in the table below. Detailed directions for reading Bicillin L-A labeling to identify affected product lots are available in the Pfizer Recall Notice. Providers should discontinue use of, and immediately quarantine, any affected stock. Upon quarantining affected products, promptly contact Sedgwick at 800-805-3093 to obtain pre-paid shipping labels to return them.

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 2,400,000 units/ 4 mL	10 (2 mL) syringes per carton, 24 cartons per shipping case  10 (4 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		
		GT2599	260930		
		HR9969	270430		
		HK2909	270228		
		HR9984	270831		

This recall exacerbates the ongoing <u>shortage</u> of Bicillin L-A first announced by the Food and Drug Administration in April 2023 and expected to last at least until the fall of 2025. Reduced Bicillin L-A inventory is a considerable concern as NYC continues to have high rates of syphilis, including syphilis in pregnant people and congenital syphilis. Bicillin L-A is the recommended, first-line treatment for syphilis, and the only recommended treatment for pregnant people.

## The NYC Health Department recommends the following to conserve supplies as this recall reduces inventory of Bicillin L-A:

- Prioritize Bicillin L-A stock for pregnant patients with syphilis infection or exposure and with a congenital exposure. <u>Treatment decisions for infants</u> should be informed by adequacy of maternal treatment; presence of clinical, laboratory, or radiographic evidence of syphilis in the neonate; and comparison of maternal (at delivery) and neonatal nontreponemal serologic titers.
- 2. Prioritize Bicillin L-A for patients with contraindications to doxycycline (e.g., anaphylaxis, hemolytic anemia, Stevens Johnson syndrome).
- 3. If your Bicillin L-A inventory is low, consider treating non-pregnant adult patients with primary, secondary, or early latent syphilis with doxycycline 100 mg PO BID x 14 days. Strongly consider treating non-pregnant adult patients with late latent syphilis or syphilis of unknown duration with doxycycline 100 mg PO BID x 28 days.
- 4. Perform follow-up clinical and serologic evaluation after treatment at recommended intervals, per the CDC's 2021 STI Treatment Guidelines. Schedule a follow-up upon the patient's post-doxycycline course to verify if treatment was completed and if there was a decline in titer, indicating that the infection was adequately treated.
- 5. Do not use other intramuscular formulations of penicillin, including Bicillin C-R, as they are not acceptable alternatives for the treatment of syphilis.
- 6. Avoid using Bicillin L-A for treatment of other infectious diseases (e.g., streptococcal pharyngitis) as alternative oral medications or other effective antimicrobials are available.
- 7. If your institution is experiencing a Bicillin L-A shortage, contact the NYC Health Department by emailing <a href="mailto:stitraining@health.nyc.gov">stitraining@health.nyc.gov</a> with the name of your facility and 'Bicillin L-A shortage' in the subject line. We will advise on other facilities with adequate supplies where patients can be directed for treatment.
- Access current and historical syphilis test results and treatment information in the NYC
   Health Department's <u>Syphilis Registry</u> to inform diagnosis and management of syphilis in
   your patients.

<u>Extencilline</u> and <u>Lentocilin</u> were approved by FDA for temporary importation due to prior shortages and remain available if you experience challenges procuring sufficient Bicillin L-A.

For clinical questions related to the treatment of syphilis amidst any Bicillin L-A shortage, please contact the <u>STD Clinical Consultation Network</u>, or the NYC Health Department at <u>stitraining@health.nyc.gov</u>.

Sincerely,

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Executive Director, Sexually Transmitted Infections Program Bureau of Hepatitis, HIV, and Sexually Transmitted Infections