



U.S. CENTERS FOR DISEASE
CONTROL AND PREVENTION

STI Updates

Dear Colleagues,

CDC has been alerted of a [new voluntary recall](#) by King Pharmaceuticals LLC., a subsidiary of Pfizer, of specific referenced lots of **Bicillin® L-A** (Penicillin G Benzathine Injectable Suspension). Penicillin is the only recommended treatment for pregnant women and babies with congenital syphilis. Considering this recall and high levels of [syphilis diagnoses](#) in the United States, we anticipate a limited supply of Bicillin® L-A. Given this information, we recommend that jurisdictions strongly consider preserving Bicillin® L-A for treating patients who are pregnant until we learn more about the impact of the recall given the dynamic nature of the situation.

Pfizer is initiating this recall due to particulates identified during visual inspection. The lots included are listed below this e-mail. Pfizer is still working to determine the impact of the recall on their production timeline.

Pfizer has completed a Health Hazard Assessment [which indicated](#) that the potential risk to patients from use of the impacted product is medium. To date, we are not aware of any adverse events associated with this issue and there is no indication at this time of reduced efficacy or need for retreatment.

We recognize that jurisdictions may be affected by this recall and could experience challenges procuring enough Bicillin® L-A to meet their needs. [Extencilline](#) and [Lentocilin®](#) were approved by FDA for temporary importation due to prior shortages and remain available.

As we await resolution of this issue, it remains critical that potentially limited inventory be used to treat the patients who need it most.

CDC strongly encourages the following actions:

1. Identify whether you have current inventory of the recalled product and [follow the guidance issued by the manufacturer](#).
2. Take inventory:
 - a. Monitor local supply of Bicillin® L-A and [determine the local pattern of use to forecast need](#).

- b. Continue to contact distributors to procure Bicillin® L-A as appropriate. [Contact Pfizer to request product](#) through their Medical Request Process if the distributor has no supply.
- 3. Prioritize using Bicillin® L-A to treat women with syphilis during pregnancy, as penicillin is the only recommended treatment for pregnant women and babies with congenital syphilis.
 - a. Choose doxycycline for men and non-pregnant women to help preserve Bicillin L-A® supplies. Doxycycline can be given at a dose of 100mg orally two times a day for two weeks (for early syphilis) or for four weeks (for late latent syphilis or latent syphilis of unknown duration). See [CDC's treatment guidelines](#) for more information.
 - b. Consider involving antimicrobial stewardship leaders to help institute systems-level approaches to limit the use of Bicillin® L-A and encourage the use of alternative effective antimicrobials for treatment of other infections.
 - c. Bicillin L-A® is one of the preferred prophylactic regimens for patients with acute rheumatic fever or rheumatic heart disease to reduce the likelihood of recurrent Streptococcal infections and acute rheumatic fever episodes. Twice daily administration of oral penicillin V is an alternative option for prophylaxis as detailed in [Clinical Guidance for Acute Rheumatic Fever | Group A Strep | CDC](#).
- 4. Accurately stage syphilis cases to ensure appropriate use of antimicrobials. Early syphilis (primary, secondary, and early latent) only requires one dose of 2.4 million units of Bicillin® L-A, including during pregnancy. See the [CDC STI Treatment Guidelines](#). A few reminders:
 - a. A thorough physical exam is necessary to accurately stage syphilis. Primary lesions may be hidden inside the mouth, anus, or vagina; signs of secondary syphilis may be found on the skin, mouth, or anogenital area (i.e., mucus patches, condyloma lata). The rash of secondary syphilis can be subtle.
 - b. Prior syphilis serologic test results can assist with staging a patient with latent syphilis as early latent, if there is evidence of new infection within the last year (i.e., new seroconversion or a sustained four-fold increase in RPR titer in a person who has had syphilis in the past).
 - c. Reviewing signs and symptoms and sexual partner history from the past 12 months can assist with determining the likelihood of syphilis acquisition

within the last 12 months, which also only requires one dose of Bicillin® L-A (2.4 million units) instead of three doses (7.2 million units).

- d. You can find resources for appropriately staging syphilis from [the National STD Curriculum](#) (NSTDC) and [the New York City Department of Health and Mental Hygiene Bureau of Sexually Transmitted Infections/New York City STD Prevention Training Center](#).
5. Communicate with healthcare providers and pharmacists.
 - a. Notify healthcare providers and pharmacists of the limited availability of Bicillin® L-A so they are aware and can plan appropriately.
 - b. Clinicians with questions about syphilis clinical management should contact an Infectious Diseases specialist or [the online National Network of STD Clinical Prevention Training Centers \(NNPTC\) STD Clinical Consultation Network](#).
6. Notify DSTDP and FDA of any shortage of Bicillin® L-A so we can continue to monitor this situation.
 - a. If you are a *Strengthening STD Prevention and Control for Health Departments* (STD-PCHD) funding recipient and have questions about any of this information or need assistance, please contact your project officer.
 - b. For other groups who are encountering challenges securing this drug to treat women with syphilis during pregnancy, please contact stdshortages@cdc.gov.

We appreciate all your hard work to prevent and address syphilis.

Sincerely,

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Lots included in this recall:

Table showing the lots included in this recall

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		
		HK2909	270228		
		HR9984	270831		