

HEALTH ALERT

JB Pritzker, Governor

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Pfizer Recall and Bicillin L-A® Shortage Alert

Summary and Action Items

The purpose of this Health Alert is to:

- 1. Share Pfizer recall of multiple lots of Bicillin.
- 2. Provide recommendations for how to prioritize Bicillin stock.
- 3. Review alternatives to Bicillin and how they can be acquired.

Background

On July 10, 2025, Pfizer announced a <u>voluntary recall</u> of multiple lot numbers of Benzathine Penicillin G (Bicillin L-A®). This recall is due to medication not meeting visual inspection standards. While there have been no received reports of any adverse events associated with the issue, Pfizer advises discontinue use of impacted lot numbers. Subsequently, on July 14, 2025, the Food and Drug Administration (FDA) issued a <u>Drug Shortage Alert</u> for this critical medication. Pfizer is currently assessing the impact of the recall on production timelines. Health care providers should prepare for a potentially prolonged shortage.

This shortage poses a significant public health concern. Bicillin L-A® is the only recommended treatment for syphilis in pregnancy. Over the past five years, the rate of congenital syphilis in the United States has surged by 203%. According to 2023 CDC surveillance data, Illinois ranks 22nd in the nation for congenital syphilis rates.

Recommendations

Bicillin L-A® remains the first-line treatment for all syphilis cases and the only option for certain patient populations. In light of the shortage, programs should take the following steps.

- Continue to follow <u>CDC STI Treatment Guidelines</u> for appropriate management, including staging, of syphilis cases.
- **Prioritize** Bicillin L-A® for pregnant individuals who have been infected or exposed to syphilis as it is the only recommended treatment in these cases.
 - For pregnant patients, Refer to the <u>Perinatal Syphilis Warmline</u> (800.439.4079) as needed for clinical consultation, coordination of record searches for prior syphilis testing and treatment and assistance with mandatory case reporting.
 - o Individuals who have already initiated treatment with a 3-week course of Bicillin L-A®
 - For non-pregnant patients, Doxycycline may be used as an alternative.
 - 100 mg PO twice daily for 14 days for early syphilis.
 - 100 mg PO twice daily for 28 days for late latent syphilis or syphilis of unknown duration.

Illinois Department of Public Health

525-535 W. Jefferson St. Springfield, IL 62761 dph.illinois.gov 217-557-2556 69 W. Washington St., Suite 3500 Chicago, IL 60602 If a provider has a non-pregnant patient who requires Bicillin treatment (e.g. Doxycycline allergy) please assess whether they could obtain Bicillin at an alternate site in a timely manner to avoid delays in treatment, including a nearby <u>FQHC</u> or <u>Free and Charitable Clinic</u>.

Health Care providers are encouraged to act promptly and coordinate with their <u>local public health</u> officials to ensure priority access for at-risk populations.

Bicillin L-A® Current Distribution Process:

Effective immediately, all Bicillin L-A® 1.2 million unit and 2.4-million-unit formulations will be available exclusively through Pfizer's Medical Request process. For these detailed instructions and access to the request form, please refer to Pfizer's official supply update letter: <u>Pfizer Availability Update for Bicillin L-A® (July 2025)</u>. Pfizer will allocate its limited inventory based on clinical necessity. To obtain product, health care providers must complete a <u>Medical request form</u> on a per-patient basis. Fulfillment will be limited to requests for patients with confirmed cases of congenital syphilis or those at risk for congenital syphilis.

Completed forms should be submitted via email to: <u>PISupplyContinuity@pfizer.com</u>.

Alternatives

If warranted due to the drug shortage, health care providers may consider use of Extencilline®, Lentocilin® or alternate treatment with doxycycline. Extencilline® is equivalent to Bicillin L-A® and its use has been recommended in pregnancy during times of Bicillin L-A® shortage.

Ordering Extencilline ®

To address the shortages of Bicillin L-A® in the United States, Laboratories Delbert & Provepharm Inc. in coordination with the U.S. Food and Drug Administration (FDA) are temporarily importing Extencilline© (Benzathine Benzylpenicillin) Powder and diluent for suspension for injection, 1,200,000 units and 2,400,000 units into the United States. Benzathine benzylpenicillin is another name for Penicillin G benzathine.

To place an order, please contact one of the authorized distributors below: Mckesson Corporation, Cencora Global Procurement Ltd., Cardinal Health, Morris & Dickson, Anda Inc., Henry Schein, OptumRx, Direct Success Inc (<u>Distribution@DSuccess.com</u> or 1-877-404-3338.)

For more information, please review the FDA Healthcare Provider Letter regarding Extencilline®

Instructions on how to prepare and administer Extencilline®.

Ordering Lentocilin®

To address the shortages of Bicillin L-A® in the United States, Mark Cuban Cost Plus Drug Company in coordination with the U.S. Food and Drug Administration (FDA) are temporarily importing Lentocilin© (Benzathine Benzylpenicillin Tetrahydrate) Powder and diluent for suspension for injection, 1,200,000 units into the United States. Benzathine benzylpenicillin is another name for Penicillin G benzathine.

To place an order, please contact TopRx at support@toprx.com or 1-800-542-8677.

For more information, review the FDA Healthcare Provider Letter regarding Lentocilin®.

Contact

IDPH Sexually Transmitted Infections Section at 217.782.2747

Target Audience

Local Health Departments, Local EMAs, Hospital/ Clinics, Providers, and FQHCs, ED personnel, infectious disease staff, medical staff, nurses/nursing directors, pharmacy staff, health care coalition, correctional/detention facilities, women's health, pediatricians, IL licensed pharmacists

IDPH CD Leads and Staff, IDPH RHOs, IDPH OPR Leads, IDPH ERCs, IDPH Regional EMS Coordinators, IDPH Health Care Associated Infection Team, HFS, State Board of Health, and IDPH HAN Team

Date Issued

July 17, 2025

Resources

CDC STI Treatment Guidelines

Perinatal Syphilis Warmline

IDPH Syphilis Action Toolkit