

#### Overview

King Pharmaceuticals LLC., a subsidy of Pfizer, has issued a voluntary recall dated July 10, 2025, for select lots of **Bicillin® L-A** (Penicillin G benzathine injectable suspension) due to the presence of particulates identified during visual inspection. The affected lots were distributed between **December 11, 2023, and June 24, 2025**. A link to Pfizer's recall letter can be found here.

To date, no adverse events have been reported. However, due to potential safety concerns, public health authorities and clinical providers are instructed to immediately review and quarantine affected inventory.

#### See page 4 of this pdf for the affected lot numbers.

## **Expected Shortage and Prioritization Guidance**

This recall is anticipated to result in a national Bicillin<sup>®</sup> L-A shortage. Until further notice, remaining supplies should be prioritized for:

## Pregnant individuals with syphilis

#### Infants diagnosed with congenital syphilis

Choose doxycycline for non-pregnant patients to help preserve Bicillin<sup>®</sup> L-A supplies. Clinicians should refer to <u>CDC guidelines</u> for guidance on syphilis treatment options.

No pregnant person who needs syphilis treatment should go without Bicillin. Pfizer will distribute available inventory in accordance with its medical request process, which requires that customers complete a <u>medical request form</u> to request product on a per patient basis. If you become aware of cases in which pregnant patients are not receiving Bicillin due to the shortage, please contact the OHA STD Program immediately for CDC reporting purposes.

This is a terrible time to waste Bicillin. Appropriately stage syphilis cases to ensure responsible use of antimicrobials. Early syphilis (primary, secondary and early latent) only requires one dose of 2.4 million units of Bicillin<sup>®</sup> L-A. If you have more Bicillin than you can use before it expires and you are able to share your supply with other sites within or outside your agency, please do so to maximize the number of people with early (infectious) syphilis treated with Bicillin.

Extencilline and Lentocilin have received FDA temporary importation approval due to ongoing Bicillin<sup>®</sup> L-A shortages. Clinicians and pharmacies should consider these alternatives where appropriate. Please note that the preparation and administration of Extencilline and Lentocilin, as well as the contraindications for prescribing, differ from those for Bicillin<sup>®</sup> L-A.

To place an order for **Extencilline**, contact Direct Success at <a href="mailto:Distribution@dsuccess.com">Distribution@dsuccess.com</a> or 1-877-404-3338. For additional information related to the product, please contact Provepharm, the U.S. distribution partner, at <a href="mailto:medicalaffairs@provepharm.com">medicalaffairs@provepharm.com</a> or 610-601-8600. CDC information on Extencilline can be found <a href="mailto:here">here</a>. Extencilline is NOT eligible for discounted purchasing via the 340B Drug Pricing Program.

To place an order for **Lentocilin**, also not likely to be eligible for the 340B Drug Pricing Program, contact TopRx at <a href="mailto:support@toprx.com">support@toprx.com</a> or 1-800-542-8677. Information regarding Lentocilin can be found here.

#### **Returning Recalled Product**

If you have any of the affected lots in your inventory, please discontinue use, stop distribution and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8637. Contact Sedgwick at 800-805-3093 (Mon.-Fri. 8 a.m.-5 p.m. ET) to obtain pre-paid shipping labels to initiate the return process. All returns are requested to be completed within six months of the recall notice date. If you have further distributed the recalled product, please notify your accounts and/or additional locations which may have received the recalled product. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution and quarantine the affected product. Reimbursement for the returned product will be made by credit memorandum. Contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 a.m.-6 p.m. ET) or your Pfizer representative regarding product availability and questions regarding this market action.

If your organization has affected Bicillin® L-A received directly from the Oregon Health Authority (OHA), please contact <u>Jillian Garai</u> to discuss return of the product. Please note OHA's stock is recalled. We are attempting to procure additional product.

#### **Pfizer Customer Letter and Medical Request Form**

Additional information from Pfizer regarding the current Bicillin<sup>®</sup> L-A supply and how to order additional product can be found <u>here</u>.

Thank you for your prompt attention to this matter and for your ongoing dedication to protecting Oregon communities. Please disseminate this alert as appropriate within your local public and tribal health networks. Reach out to <a href="mailto:pete.p.singson@oha.oregon.gov">pete.p.singson@oha.oregon.gov</a> with questions or concerns about the above information.

Pete P. Singson, MD

HIV/STD/TB Medical Director OREGON HEALTH AUTHORITY

Public Health Division Cell: 503-358-3377

Email: <a href="mailto:pete.p.singson@oha.oregon.gov">pete.p.singson@oha.oregon.gov</a>

http://www.oregon.gov/OHA

Unless otherwise noted, feel free to share this HAN notification with:

- Others within your organization.
- Professionals within your health, preparedness, and response affiliations.

**Oregon 24/7 disease reporting: 971-673-1111** 

## **HEALTH ALERT NETWORK MESSAGE**

**Date:** July 14, 2025

Subject: Bicillin® L-A Product Recall – Urgent Inventory Review and Clinical Guidance

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### **Affected Lot Numbers**

Bicillin® L-A

Penicillin G Benzathine Injectable Suspension

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		

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- To place an order for Extencilline, contact Direct Success at
   <u>Distribution@dsuccess.com</u> or 1-877-404-3338. For additional information related to
   the product, please contact Provepharm, the U.S. distribution partner, at
   <u>medicalaffairs@provepharm.com</u> or 610-601-8600. CDC information on Extencilline
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