



Pfizer Inc.  
275 North Field Drive  
Lake Forest, IL 60045

February 12, 2020

Voluntary Product Withdrawal Request  
of Bacitracin for Injection, USP From the Market

Dear Valued Customer,

The U.S. Food and Drug Administration (FDA) has requested that all current manufacturers of Bacitracin for Injection voluntarily ask the FDA to withdraw approval of the license of Bacitracin for injection because other effective FDA-approved treatments are available that do not have the same serious risks, including nephrotoxicity (harm to the kidneys), anaphylactic reactions and the need for repeated intramuscular injections, as Bacitracin for Injection. FDA believes that the potential problems associated with Bacitracin for Injection are sufficiently serious to remove the drug from the market. The voluntary withdrawal of Bacitracin for Injection, USP, affects presentations listed below. For your awareness, the FDA posted a communication on Friday, January 31, found [here](#).

It is important to note that **FDA is not requiring a recall**, which would involve product removal and/or return. While Pfizer will cease manufacturing Bacitracin Injection, we will continue to distribute product until our current inventory is exhausted.

The product NDC presentations impacted are listed in the below table. Pfizer will continue to monitor the inventory levels and is committed to provide an update once inventory levels approach depletion.

Unit of Sale NDC	Product Description
00009-0233-45	Bacitracin for Injection, USP 50,000 Units Amerinet Vial 10s
00009-0241-10	Bacitracin for Injection, USP 50,000 Units PREMIERProRx® Vial 10s
00009-0233-44	Bacitracin for Injection, USP 50,000 Units Amerinet Vial 1s
00009-0241-01	Bacitracin for Injection, USP 50,000 Units PREMIERProRx® Vial 1s
00009-0233-01	Bacitracin for Injection, USP 50,000 Units Vial 1s
00009-0233-03	Bacitracin for Injection, USP 50,000 Units Vial 10s

To review the most up-to-date information on product availability, please download the Availability Report from our [PfizerHospitalUS.com](http://PfizerHospitalUS.com) website. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT, M - F, to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]).

For medical inquiries related to the above product, please contact Pfizer Medical Information at 1-800-438-1985. Please reach out to your Pfizer Hospital sales representative or sales executive if you have any other questions.

Thank you,

Jack Brown  
Portfolio Director Anti-Infectives and ADD-Vantage  
Pfizer Hospital Business Unit U.S.