Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi/us

March 2, 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, USP voluntarily withdraw their applications 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. The FDA believes that the potential problems associated with Bacitracin for Injection are sufficiently serious to remove the drug from the market, but **it is significant to note the FDA is not requiring a recall**.

The full FDA communication posted January 31, 2020 can be found at:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-bacitracin-injection-market

Accordingly, Fresenius Kabi has notified the FDA of our decision to voluntarily withdraw our FDA-approved Bacitracin for Injection application, as well as our decision to cease manufacturing of the product. **We will continue to distribute product until current inventory is depleted.**

Specific information related to the impacted product presentation is listed below:

NDC Number	Material Description
63323-329-31	**Bacitracin for Injection, USP 50,000 units MDV**

For product-availability updates, please visit our web site at www.fresenius-kabi.com/us/pharmaceutical-product-availability, or call our Customer Service team at 1-888-386-1300.

For clinical questions, please contact Fresenius Kabi USA Medical Affairs at 1-800-551-7176, Monday-Friday between 8 a.m. and 5 p.m. (CST) or email medinfo.USA@fresenius-kabi.com.

Sincerely,

Byron Dougherty
Marketing Manager, Anti-Infectives
Fresenius Kabi USA, LLC