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Pharmacy Safety Alert

March 9, 2016

Teva Pharmaceuticals Initiates Voluntary Recall of One Lot of Amikacin Sulfate Injection USP, 1 gram/4mL (250 mg/mL) Vials Due to the Potential Presence of Glass in One Vial.

NORTH WALES, Pa. – Teva Pharmaceuticals today announced a voluntary recall of one lot of amikacin sulfate injection USP, 1 gram/4mL (250 mg/mL) vials due to the potential presence of particulate matter identified as glass in one vial. The recalled lot is:

Lot #	Exp. Date	Vial Size	NDC # (Individual Pack)	NDC # (Shelf Pack)
4750915	9/2017	1 gram/4 mL (250 mg/mL)	0703-9040-01	0703-9040-03

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected. To date, Teva has not received any reports of adverse events or complaints related to this recall.

Amikacin sulfate injection USP is used in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, and has also been shown to be effective in staphylococcal infections and may be considered as initial therapy under certain conditions in the treatment of known or suspected staphylococcal disease. Amikacin sulfate injection is in a class of medications called aminoglycoside antibiotics and is packaged in pharmacy bulk packages, containing ten 1 gram/4 mL (250 mg/mL) vials per shelf pack. Amikacin sulfate injection 250 mg/mL, 4 mL vials were distributed nationwide through wholesalers, retailers and pharmacies.

Teva has issued an Urgent Drug Recall Letter to their direct customers. Teva is arranging for impacted product to be returned to Inmar. Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all retail and medical facility accounts. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities.

For medical related questions please contact Teva Medical Information at 888-838-2872, option 3, then, option 4. For a customer service related question, please contact Teva Customer Service at 800-545-8800 Monday – Friday; 8:00 AM – 5:00 PM EST. Consumers should immediately contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product. For product quality complaint-related questions please contact Teva Quality Assurance Services at 888-838-2872, option 3, then, option 3.

Adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report
    - **Online**: www.fda.gov/medwatch/report.htm
    - **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.