

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

**PBM-2016-06**

**AUGUST 8, 2016**

**ITEM:** Amikacin Sulfate Injection USP 500mg/2mL (250mg/mL) and 1 gram/4mL (250mg/mL): Recall due to Potential for Glass Particulate Matter in Vials

**SPECIFIC INCIDENT(S):** Teva Pharmaceuticals announced a voluntary recall of seven lots of Amikacin Sulfate Injection USP, 500 milligram (mg) / 2 milliliter (mL) [250mg/mL] and 1 gram (gm) / 4mL [250 mg/mL] vials due to the potential presence of glass particulate matter.

**GENERAL INFORMATION:**

- Amikacin is an aminoglycoside antibiotic indicated in the short-term treatment of serious infections caused by susceptible strains of Gram-negative bacteria as well as in the treatment of staphylococcal infections.
- The administration of a glass particulate, if present in an intravenous drug or used in nebulization, may result in local irritation or swelling in response to the foreign material as well as blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.
- Affected products and lots are included below:

Lot#	Exp. Date	Strength	Vial Size	NDC# (Individual Pack)	NDC# (Shelf Pack – carton of 10 vials)
2381114	11/2016	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
2771114	11/2016	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
4760915	9/2017	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
7080315	3/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03
7400315	3/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03
7410315	3/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03
7980415	4/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 11020** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html> ).
- Providers should continue to report any adverse reactions with the intravenous or nebulized use of amikacin sulfate injection USP, 500 mg/2 mL (250mg/mL) and 1 gm/4mL (250 mg/mL) vials by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA

MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

**ACTIONS:**

**PROVIDER NOTIFICATION:**

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, infectious disease specialists, pulmonologists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

**PATIENT NOTIFICATION:**

- **Chief of Pharmacy:** Within 10 business days of issue (due 8/22/2016):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration via intravenous or nebulized route. Sites may not have lot number information available locally, so in the case that the lot number data is not available, sites will need to call all patients that received the product and ask them to check the lot numbers.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: <https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to use the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.

- Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:  
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

**SOURCE:** FDA

**REFERENCE(S):** FDA Recalls, Market Withdrawals, & Safety Alerts. Teva Pharmaceuticals Initiates Voluntary Nationwide Recall of Seven Lots of Amikacin Sulfate Injection USP 500 mg/2 mL (250 mg/mL) and 1 Gram/4 mL (250 mg/mL) Vials Due to Potential of Glass Particulate Matter.  
[http://www.fda.gov/Safety/Recalls/ucm514656.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Safety/Recalls/ucm514656.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery) . Accessed August 4, 2016.

**ATTACHMENT(S):** None.

**CONTACTS:** Pharmacy Benefits Management Services (PBM) at (708)786-7862.