

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

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

**PBM-2016-05**

**EXPANSION**

**AUGUST 4, 2016**

**ITEM:** Bactroban (Mupirocin): Recall due to Potential for Contamination during Manufacturing Process

**SPECIFIC INCIDENT(S):** In September 2015, GlaxoSmithKline voluntarily recalled certain lots of Bactroban (mupirocin calcium) cream, ointment, and nasal ointment due to cross contamination of penicillin and other foreign substances during the manufacturing process. Last December 2015, additional lot numbers were added to the original recall from September. Currently, the manufacturer continues to identify new lots that have been affected. Affected product started shipping October 2014.

**GENERAL INFORMATION:**

- Bactroban (mupirocin calcium) cream or ointment is a topical antibiotic used for the treatment of skin infection. Bactroban (mupirocin calcium) nasal ointment is an antibacterial drug indicated for the eradication of nasal colonization with methicillin-resistant *Staphylococcus aureus* (MRSA).
- Patients sensitive to penicillin exposed to affected lots of this product may be at risk for experiencing an allergic reaction.
- Additional affected products and lots are included below:

Description	Lot #/ Exp Date	NDC	UPC	Econo #
BACTROBAN CRM 2% 15GM	C725860 11/30/16; C740904 02/28/17;	00029152722	30029152722	2177020
BACTROBAN CRM 2% 30GM	C740906 02/28/17	00029152725	30029152725	2177319
BACTROBAN NASAL OINT 2% 1GM 10	C686801 07/31/16; C689267 07/31/16;	00029152611	30029152611	1485978
	C692405 07/31/16; C698116 09/30/16;			
	C750793 11/30/17; C750794 11/30/17;			
	C752166 11/30/17; C752805 11/30/17;			
	C754828 11/30/17;			
BACTROBAN OINT 2% 22GM	C715275 08/31/16	00029152544	30029152544	1139245

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10997** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of Bactroban (mupirocin calcium) cream, ointment, and/or nasal ointment 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, 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 8/18/2016):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by a CMOP representative to Pharmacy Chiefs.
  - 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):** 1. McKesson Important Notice Urgent Recall. RC: 16-109A. July 25, 2016.

**ATTACHMENT(S):** None.

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

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