NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

ADDENDUM

PBM-2015-08 **DECEMBER 17, 2015**

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. Recently, additional lot numbers were added to the original recall from September.

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.
- Affected products and lots are included below:

Description	Lot #	Exp Date	NDC
BACTROBAN CRM 2% 15GM	C695549	03/31/16	0029152722
	C707837	07/31/16	
	C718210	09/30/16	
BACTROBAN OINT 2% 22GM	C698039	03/31/16	0029152544
BACTROBAN CRM 2% 30GM	C707836	07/31/16	0029152725
	C718209	09/30/16	
BACTROBAN NASAL OINT 2% 1GM 10	C704202	11/30/16	0029152611
	C706532	12/31/16	
	C713177	01/31/17	
	C716567	02/28/17	
	C720096	02/28/17	
	C720097	03/31/17	
	C720098	03/31/17	
MUPIROCIN CALCIUM CREAM, 2%, 15GM AND 30GM	C690076, C693373	02/28/16	66993-942-15 and 66993-942-31
	C701378, C701376	04/30/16	
	C704164	05/31/16	
	C713687	08/31/16	
	C719467, C718203	09/30/16	
	C723641	10/31/16	
	C683884	12/31/16	
	C697653	03/31/16	
	C710477	07/31/16	

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- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10013** (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 12/31/2015):
  - 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.

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- 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. FDA Enforcement Report – Week of September 2, 2015. http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=select&recall_number=D-1362-2015&w=09022015&lang=eng . (Accessed 12/15/2015)
2. GSK Urgent Drug Recall. http://www.smithdrug.com/uploads/recalls/bactroban.pdf . (Accessed 12/15/2015)

ATTACHMENT(S): None.

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