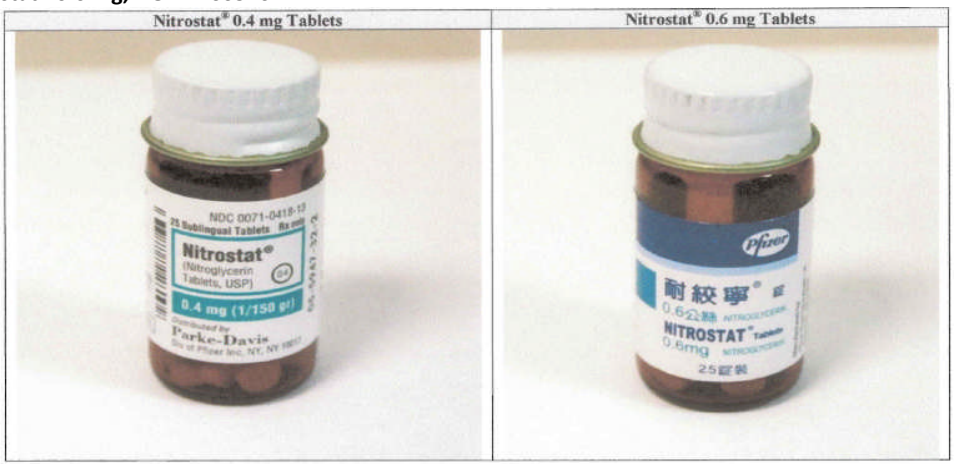
DEPARTMENT OF VETERANS AFFAIRS VETERAN HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) & MEDICAL ADVISORY PANEL (MAP)
VA CENTER FOR MEDICATION SAFETY (VAMedSAFE)

NATIONAL PBM COMMUNICATION · May 25, 2011

Nitroglycerin (Nitrostat®) Recall Due to Packaging Error

- Pfizer Inc., is voluntarily recalling the following medicines due to incorrect packaging:
  - **Nitrostat® 0.4 mg, LOT V100670**
  - **Nitrostat® 0.6 mg, LOT V100546**



- Four-pack cartons of **Nitrostat® 0.4 mg, LOT V100670** may contain bottles of **Nitrostat® 0.6 mg, LOT V100546**, which are not marketed in the United States.
- No other lot number(s) are affected by this recall.
- According to Pfizer, patients who inadvertently take **Nitrostat® 0.6 mg** instead of **Nitrostat® 0.4 mg** may experience adverse effects that are temporary and medically reversible, with serious outcomes a remote possibility.

SEQUESTERING ACTIONS

- Following the action due dates in Product Recall Office Log # 1291 (available at http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining product at the CMOP/facility level with the affected lot number per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot number(s) (refer to lot number[s] provided above) was dispensed to any patient(s) for home administration using a 12-month time frame. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.

PHARMACY ACTIONS

- If an affected lot(s) was dispensed to a/multiple patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - A sample letter can be found at:

http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc

    - This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of medication.
    - How to return the medication being recalled to the pharmacy.
- Providers should continue to report any adverse events with nitroglycerin by entering the information into CPRS' Allergies/Adverse Reactions field and/or via local reporting mechanisms. Facilities should continue to report adverse events into VA ADERS and to the FDA (as appropriate).

REFERENCES:

Nitrostat® (nitroglycerin) Sublingual Tablets [package insert]. NY, NY: Pfizer, Inc.; December 2005.

ACTIONS:

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers and cardiologists,*** *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. Report completion of actions to the Facility Director.*
- ***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).*
- ***VISN Directors:*** *Within 10 business days of receipt (due 06/09/2011), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*