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 · March 31, 2011

Citalopram and Finasteride Recall Due to Mislabeling

- Greenstone LLC is voluntarily recalling the following medicines with lot number FI0510058-A on the label due to incorrect labeling:
  - Citalopram 10mg Tablets (100-count bottle)
  - Finasteride 5mg Tablets (90-count bottle)
- Bottles labeled as Citalopram Lot # FI0510058-A may contain Finasteride.
- No other lot number(s) are affected by this recall.
- Patients who inadvertently take Finasteride instead of Citalopram may experience:
  - Changes in mood or behavior due to the sudden discontinuation of Citalopram;
  - Possible worsening of their depression symptoms;
  - Risk to male fetus in women who are or may be pregnant and handle Finasteride.

- Following the action due dates in Product Recall Office Log # 1077 (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 (refer to lot number provided above) was dispensed to any patient(s) for home administration. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot 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 Finasteride or Citalopram 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:

FDA Firm Press Release. http://www.fda.gov/Safety/Recalls/ucm248552.htm . (Accessed March 30, 2011).
PROSCAR® (Finasteride) Tablets [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2010.

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 behavioral and mental health specialists,*** *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 4/14/2011), 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.*