

NATIONAL PBM COMMUNICATION • March 31, 2011

Citalopram and Finasteride Recall Due to Mislabeling

- Greenstone LLC is voluntarily recalling the following medicines with lot number F10510058-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 # F10510058-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.