

NATIONAL PBM COMMUNICATION · March 10, 2014

Effexor XR 150 Mg Extended-Release Capsules (Pfizer) and Venlafaxine HCl 150 Mg Extended-Release Capsules (Greenstone): Recall - Possible Presence of Tikosyn Capsules

- A pharmacist report stating that one bottle of Pfizer's Effexor XR contained one capsule of Tikosyn (dofetilide) 0.25mg in addition to the Effexor XR capsules has led to the voluntary recall of:
 - one lot of 30-count Effexor XR (venlafaxine HCl) 150 mg extended-release capsules;
 - one lot of 90-count Effexor XR (venlafaxine HCl) 150 mg extended-release capsules; and
 - one lot of 90-count Greenstone LLC-branded Venlafaxine HCl 150 mg extended-release capsules.
- Dofetilide (Tikosyn) is an antiarrhythmic drug whose initiation or reinitiation requires close monitoring (i.e., minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation) to prevent risk of induced arrhythmias. If inadvertently taken, conduction disturbances which could lead to fatal outcomes in at-risk patients who are not appropriately followed may occur.

PRODUCT SEQUESTERING ACTIONS

- This patient level recall involves Pfizer lot numbers V130142 and V130140, which both expire in October 2015, and Greenstone lot number V130014, which expires in August 2015.
- Following the action due dates in **Product Recall Office Log # 7968** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) 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(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact patient(s) who may have received the affected product(s) for home administration by any appropriate method.
 - A sample letter can be found at:
<https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc>
 - 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.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
 - Effexor XR/Venlafaxine HCl 150mg is an opaque dark orange, locking type, elongated hard gelatin capsule:



- The incorrectly contained Tikosyn (dofetilide) is a peach/peach opaque, locking type, hard gelatin capsule:



- Providers should continue to report any adverse reactions with the use of Effexor/venlafaxine or Tikosyn (dofetilide) 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).

REFERENCES:

1. Effexor XR 150 Mg Extended-Release Capsules (Pfizer) and Venlafaxine HCl 150 Mg Extended-Release Capsules (Greenstone): Recall - Possible Presence of Tikosyn Capsules. <http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm388352.htm>. (Accessed 03/07/2014)
2. Pfizer Initiates Nationwide Voluntary Recall of Two Lots of Pfizer's Effexor XR® 150 Mg Extended-Release Capsules and One Lot of Greenstone's Venlafaxine HCl 150 Mg Extended-Release Capsules Due to the Possible Presence of Tikosyn® Capsules. <http://press.pfizer.com/press-release/pfizer-initiates-nationwide-voluntary-recall-two-lots-pfizers-effexor-xr-150-mg-extend>. (Accessed 03/12/14)
3. Tikosyn (dofetilide) product package insert. NY, NY: Pfizer Labs; December 2013.

FEEDBACK NOTIFICATION 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, mental health providers, 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. 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 issue (due 03/21/2014), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx.