NATIONAL PBM COMMUNICATION · June 30, 2009

Caraco Pharmaceuticals and Urgent Drug Recall of Citalopram Due to Tablet Size Variance

- On June 16, 2009, Caraco Pharmaceuticals issued an Urgent Drug Recall for citalopram due to tablets of varying size and the possibility of the active ingredient differing from the amount specified on the label.
- This is a RETAIL level recall.
- Citalopram, indicated for the treatment of depression, may pose risk to patients if over- or under- dosed.
  - In clinical trials, doses of citalopram up to 2000mg did not result in any fatalities.
  - Symptoms of overdose with citalopram (monotherapy or in combination with other drugs/alcohol) include: *dizziness, sweating nausea, vomiting, tremor, somnolence, sinus tachycardia*.
  - Rare effects of citalopram overdose include*: amnesia, confusion, convulsions, coma, hyperventilation, cyanosis, rhabdomyolysis, ECG changes (QTc prolongation, nodal rhythm, ventricular arrhythmia, Torsades de pointes), and acute renal failure.*
  - Lower than intended doses of citalopram may result in lack of efficacy.
- The following lot number is being recalled:

PRODUCT DESCRIPTION	NDC	LOT NUMBER	ECONO #
CITALOPRAM TAB 10MG 500	57664050713	82577A	1701366

- Return all remaining product at the facility/CMOP level with the affected lot number to McKesson, NOT as instructed in the product recall documents. Affected lots of in-house stock are to be sequestered within 24 hours of this notice. Please inform your Facility Recall Coordinator when the sequestering actions have been completed.
- Determine whether the affected lot number (refer to lot number provided above) was dispensed to any patient(s). It is recommended to use a 12-month time frame for this determination. The attached VAMC data may be used as a guide (data may not include direct purchases/drop shipments). CMOP has determined that no purchases of this lot number were made.
- If the affected lot was dispensed to a patient(s), 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 affected 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.
  - To continue taking the medication with the affected lot number until they receive a new supply of citalopram. When correct medication is received, patient should begin taking the new medication and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this medication to the VA ADERS program.

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 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 07/15/2009), 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 .*