

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

NATIONAL PBM COMMUNICATION • February 3, 2012

Oral Contraceptives and Packaging Error - Recall Due to Risk of Unwanted Pregnancy

- Pfizer, Inc., is voluntarily recalling 14 lots of Lo/Ovral-28 (norgestrel and ethinyl estradiol) Tablets and 14 lots of Norgestrel and Ethinyl Estradiol Tablets (generic) for customers in the U.S. market due to a packaging error involving the blister cards:
 - Tablet sequence is out of order.
 - Number of active and inactive tablets is not exact.
- The improper order of tablets as well as the inexact number of tablets that ensued from the packaging error may lead patients to take incorrect doses within their cycle, resulting in inadequate contraception and the risk for unwanted pregnancy.
- A second, nonhormonal method of birth control (e.g. condoms) is recommended for patients who have acquired the affected products (below).

SEQUESTERING ACTIONS

- Following the action due dates in Product Recall Office Log #2096 (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 numbers per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Affected products and associated NDC numbers, lot numbers, and expiration dates appear in the following link: <http://www.fda.gov/Safety/Recalls/ucm289770.htm> .

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) 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.
- 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:
http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/OC%20Recall_Patient%20Letter%20Template.doc
This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to obtain a new supply of product.
 - How to return the product being recalled to the pharmacy.
 - When the correct product is received, patient should begin using the new product and return the recalled supply as instructed.
 - Patient should be instructed to use additional nonhormonal methods of contraception (e.g., condoms) if the patient has taken the recalled product and/or has missed doses. A prescription for condoms may be provided by VA upon patient and/or provider request.
- Providers should continue to report any adverse reactions with the use of oral contraceptives 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

FDA Recall – Firm Press Release: Pfizer Announces Voluntary Nationwide Recall of Lo/Ovral®-28 and Norgestrel/Ethinyl Estradiol Tablets Due to Possibility of Inexact Tablet Counts or Out of Sequence Tablets. <http://www.fda.gov/Safety/Recalls/ucm289770.htm> . (Accessed 01/31/12).

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, women's 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 02/17/2012), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.