



February 3, 2012

Manufacturer initiates nationwide voluntary recall of oral contraceptives

On January 31, Pfizer voluntarily recalled 14 lots of Lo/Ovral-28 (norgestrel and ethinyl estradiol) and 14 lots of Norgestrel and Ethinyl Estradiol Tablets (generic), manufactured and packaged by Pfizer Inc. and distributed by Akrimax Pharmaceuticals LLC. Some blister packs may contain an inexact count of inert or active ingredient tablets and the tablets may be out of sequence.

As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Women exposed to affected packaging should begin using a non-hormonal form of contraception immediately. Women who have the affected product should notify their physician and discuss alternative therapy. Patients with questions may contact Akrimax toll-free at 1-877-509-3935 between the hours of 8 a.m. and 7:00 p.m. CT Monday through Friday.

There are limited supplies of Lo/Ovral-28 and Norgestrel/Ethinyl Estradiol Tablets (generic) in the market place which is why it is recommended that patients discuss alternate therapy with their prescriber. The manufacturer has indicated that supplies should be available in six to eight weeks.

- **Product and strengths:** LO/OVRAL[®] 28 (norgestrel and ethinyl estradiol) and Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg
- **Indication:** for the prevention of pregnancy
- **Manufacturer:** Pfizer Inc./ Akrimax Pharmaceuticals
- **Date of recall:** January 31, 2012
- **Type of recall:** patient level
- **Reason for recall:** Some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. A retail-level recall for this issue was announced on Dec. 28, 2011. This was elevated to a patient level recall on Jan. 31, 2012.
- **NDC of recalled product:** LO/OVRAL 28: 24090-801-84; Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg: 24090-961-84
- **Affected lot numbers:** available at: <http://www.fda.gov/Safety/Recalls/ucm289770.htm>
- **Medco Pharmacy patients impacted:** approximately 22,000
- **Medco client notification:** Yes

Implications to Medco and clients

Medco is taking the following action in response to this recall:

- Quarantining lots of affected product in existing inventory and returning it to the manufacturer.
- Mailing letters to affected patients with information about the recall. Patients with impacted product will be instructed to obtain alternate therapy as there is limited supply and the manufacturer does not anticipate adequate supply to return for six to eight weeks
- Posting a message about the recall to www.medco.com
- Distributing informational and Q&A documents to customer service representatives and customer service pharmacists to aid in answering incoming questions.