# Rx Update Safety Alert

February 2012

### What You Need to Know

- Lo/Ovral-28 (norgestrel and ethinyl estradiol) tablets and its generic are being voluntarily recalled due to packaging errors
- Lo/Ovral-28 is an oral contraceptive
- Fourteen lots of the brand product and 14 lots of the generic product manufactured by Pfizer, Inc. were affected
- Patients should return the product to their pharmacy

## Lo/Ovral-28 (norgestrel and ethinyl estradiol) Voluntary Recall

### Issue:

On January 31, 2012, the U.S. Food and Drug Administration (FDA) and Pfizer, Inc. announced a voluntary recall of Lo/Ovral-28 tablets and norgestrel and ethinyl estradiol tablets (generic Lo/Ovral-28). This recall was initiated after an investigation by Pfizer, Inc. found that several blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence.

### Background:

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. These packaging defects do not pose any immediate health risks. However, consumers exposed to recalled lots should begin using a non-hormonal form of contraception immediately.

These products are packaged in blister packs containing 21 tablets of active ingredients and seven tablets of inert ingredients. Correct dosing of this product is important in avoiding the associated risks of an unplanned pregnancy.

### Product-Specific Information:

These products are oral contraceptives indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

The recalled product was distributed to wholesalers, clinics and pharmacies nationwide. This voluntary recall is a precautionary measure and the affected product is described in the table on the next page.

| Product | Package Size | NDC Number | Lot Number | Expiration Date |
|---|---|---|---|---|
| Lo/Ovral-28 (norgestrel and ethinyl estradiol) | 6 Pilpacks of 28 tablets each | 24090-801-84 | E15678 | 08/31/2013 |
| | | | E15679 | 08/31/2013 |
| | | | E15686 | 08/31/2013 |
| | | | E15687 | 01/31/2014 |
| | | | E15690 | 01/31/2014 |
| | | | E15698 | 01/31/2014 |
| | | | E15700 | 02/28/2014 |
| | | | E80434 | 07/31/2013 |
| | | | E80438 | 08/31/2013 |
| | | | F36908 | 02/28/2014 |
| | | | F36909 | 02/28/2014 |
| | | | F43915 | 03/31/2014 |
| | | | F43926 | 03/31/2014 |
| | | | F43927 | 03/31/2014 |
| norgestrel 0.3mg/ ethinyl estradiol 0.03mg | 6 Pilpacks of 28 tablets each | 24090-961-84 | E15677 | 08/31/2013 |
| | | | E15704 | 01/31/2014 |
| | | | E15706 | 01/31/2014 |
| | | | E80440 | 08/31/2013 |
| | | | F16388 | 01/31/2014 |
| | | | F16390 | 02/28/2014 |
| | | | F22132 | 02/28/2014 |
| | | | F31330 | 02/28/2014 |
| | | | F36911 | 03/31/2014 |
| | | | F36913 | 03/31/2014 |
| | | | F43924 | 03/31/2014 |
| | | | F43925 | 03/31/2014 |
| | | | F43934 | 03/31/2014 |
| | | | F53238 | 03/31/2014 |

## Recommendation:

Patients in possession of the recalled product are encouraged to: