**Norgestimate and Ethinyl Estradiol Tablets: Recall - Packaging Error, Potential for Incorrect Dosing Regimen**

**ISSUE:** Glenmark Generics Inc. issued a nationwide, consumer-level recall of seven (7) lots of Norgestimate and Ethinyl Estradiol Tablets USP (0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg), because of a packaging error where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch. 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.

**BACKGROUND:** Norgestimate and Ethinyl Estradiol Tablets are used as an oral contraceptive, indicated for the prevention of pregnancy in women. The product was distributed to wholesalers and retail pharmacies nationwide between September 21, 2011 and December 30, 2011.

**RECOMMENDATION:** Consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately. Patients who have the affected product should notify their physician and return the product to the pharmacy. See the Press Release for a listing of affected lot numbers, expiration dates, and product photos.

Read the MedWatch safety alert, including a link to the Press Release, at: