May 31, 2018

COM-2018-011

Dear provider of pharmaceutical services,

Recall: Taytulla™ (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform that on May 29, 2018 the US Food and Drug Administration (FDA) issued a statement notifying the voluntary retirement of 170,000 sample packs of Taytulla™ oral contraceptive capsule, which are manufactured by Allergan. The recall was made due to out of sequence capsules. Through a physician report, Allergan identified that four placebo capsules were placed out of order in a sample pack of Taytulla™ and the first four days of therapy had four non-hormonal placebo capsules instead of active capsules. As a result, the error may place the user at risk for contraceptive failure and unintended pregnancy. The affected lot is detailed on Table 1.

Table 1. Affected lot of sample packs of Taytulla™

Product	Affected Lot	Expiration date	NDC
Taytulla™ Softgel Capsules 1mg/20mcg Sample Packs	5620706	05/2019	Outer Carton 0023-5862-31 Blister Card 0026-5862-28 Blister Box 0026-5862-29

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that received the recalled medication in the previous 90 days.
3. Contact Allergan by phone 800-678-1605 for questions regarding this recall.

For additional information visit:

U.S. Food & Drug Administration or Allergan website at:

- https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm609064.htm
- https://www.allergan.com/investors/news/thomson-reuters/allergan-issues-nationwide-voluntary-recall-of-tay.aspx

Department of Clinical Pharmacy