



## Missouri Department of Health and Senior Services Recall Alert

The Missouri Department of Health and Senior Services received the following recall of Metronidazole Tablets. The tablets were distributed nationwide.

Original Release:

### **Teva Pharmaceuticals, U.S.A issues a voluntary nationwide recall of Metronidazole Tablets USP, 250mg Due to Low Weight Tablets**

**Contact:**

Consumer Contact  
866-262-1243  
Media Contact  
Denise Bradley  
215-591-8974

**FOR IMMEDIATE RELEASE** - January 6, 2011 - Teva Pharmaceuticals, U.S.A, is voluntarily recalling Metronidazole Tablets USP, 250mg, lot 312566, expiration date 05/2012. This product lot is being recalled due to the presence of underweight tablets.

Underweight tablets may not contain the full amount of active ingredient within a single tablet, a consumer may not receive the prescribed dose. This may cause the infection the drug was intended to treat to worsen or recur, which could be life-threatening when treating severe infections. To date, Teva Pharmaceuticals, U.S.A. has not received any adverse events associated with the use of this product lot.

Metronidazole is indicated for the treatment of symptomatic and asymptomatic trichomoniasis, and treatment of asymptomatic consorts, amebiasis and a variety of anaerobic bacterial infections. The affected Metronidazole lot is packaged in 250 count bottles and was distributed nationwide to wholesalers and retailers.

Wholesalers and retailers have been previously notified of this recall via overnight notification on 10/25/10 and are in the process of returning this product lot. Consumers who have lot 312566 in their possession are instructed to cease using the product and return it to their pharmacy. Wholesalers and retailers should cease distribution and examine their inventory immediately.

Adverse events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- **Online:** <http://www.fda.gov/MedWatch/report.htm><sup>9</sup>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm><sup>10</sup> Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Consumers with questions regarding this recall may contact 866-262-1243 from 9:00am – 5:00pm ET Monday –Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product. Teva Pharmaceuticals, U.S.A is voluntarily recalling the aforementioned product lot with the knowledge of the U.S. Food and Drug Administration.