Fareston® (toremifene) – New warnings

- On May 12, 2017, the FDA approved updates to the *Warnings and Precautions* section of the Fareston (toremifene) drug label, regarding hepatotoxicity and risk of uterine malignancy.
- Fareston is indicated for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.
- Hepatotoxicity, both increases in the serum concentration for grade 3 and 4 transaminitis and hyperbilirubinemia, including jaundice, hepatitis, and non-alcoholic fatty liver disease, have also been reported in clinical trials and postmarketing with Fareston.
    - Liver function tests should be performed periodically.
- Endometrial cancer, endometrial hypertrophy, hyperplasia, and uterine polyps have been reported in some patients treated with Fareston. Endometrial hyperplasia of the uterus was observed in animals treated with Fareston. Long-term use of Fareston has not been established in patients with pre-existing endometrial hyperplasia.
    - All patients should have baseline and annual gynecological examinations. In particular, patients at high risk of endometrial cancer should be closely monitored.
- Fareston carries a boxed warning for QT prolongation.