Toremifene Citrate (Fareston®)

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Drug name: Toremifene citrate is manufactured under the brand name Fareston® (Shire Roberts Inc., Florence, KY).

Classification: Hormone oncologic. Toremifene citrate is a nonsteroidal antiestrogen, a selective estrogen-receptor modulator. The drug is classified most commonly as an antiestrogen or antineoplastic.

Action: Toremifene citrate binds to estrogen receptors, producing estrogenic and/or antiestrogenic effects. It blocks growth of breast cancer in postmenopausal women with hormone receptor positive or unknown status.

In comparative trials, toremifene citrate had similar efficacy to tamoxifen and can be prescribed as an alternative to tamoxifen. Evidence shows that cross-resistance exists between toremifene citrate and tamoxifen, so it would be ineffective as a second-line therapy if treatment failed with tamoxifen.

Indication: The U.S. Food and Drug Administration has approved toremifene citrate for treating locally advanced or metastatic breast cancer in postmenopausal women with hormone receptor positive or unknown status.

In comparative trials, toremifene citrate had similar efficacy to tamoxifen and can be prescribed as an alternative to tamoxifen. Evidence shows that cross-resistance exists between toremifene citrate and tamoxifen, so it would be ineffective as a second-line therapy if treatment failed with tamoxifen. No data on protective heart and bone benefits are available.

Metabolism: Toremifene citrate is metabolized through the liver by the cytochrome P-450 isozyme 3A4. Metabolite shares weak antiestrogenic activity.

Excretion: Toremifene citrate is excreted in the feces (90%) and urine (10%). Elimination is slow.

Half-life: Approximately five days.

Effect on blood counts: Rare increase of liver enzymes as well as leukopenia and thrombocytopenia have been reported. Complete blood count (CBC) and liver function tests (LFTs) should be monitored periodically.

Adverse reactions and effects: The most common side effects are hot flashes, vaginal discharge, nausea, and diaphoresis and are more intense at the onset of treatment. Patients with bone metastasis may have some tumor flare (musculoskeletal pain and erythema) and an increased risk for hypercalcemia initially. A serious side effect reported with toremifene citrate is thromboembolism, but this was limited to less than 1%. Other side effects include dry eyes, dizziness, edema, vomiting, and vaginal bleeding.

Route and dosage: Toremifene citrate is administered as an oral medication with or without food. The recommended dosage is 60 mg.

Interactions: Drugs that decrease renal calcium excretion, such as thiazide diuretics, may increase the risk for hypercalcemia. Toremifene citrate has a known interaction with coumarin-type anticoagulants, increasing prothrombin times. Concurrent use with carbamazepine, phenobarbital, or phenytoin may decrease blood levels of toremifene citrate, making it less effective.

Contraindications: Toremifene citrate is contraindicated in patients with known hypersensitivity to the drug or its class or components. Caution should be used in patients with thromboembolic history and impaired liver or renal function. The drug may cause fetal harm when administered to pregnant women. Women with preexisting endometrial hyperplasia should not be given long-term toremifene citrate. No precautions or restrictions are advised for healthy older adults.

Availability: Toremifene citrate is available in 60 mg tablets. The average cost for 30 tablets is $105.99. Shire Roberts Inc. offers a patient assistance program. Patients cannot have prescription coverage—or their prescription coverage must be exhausted—to qualify. They must submit specific financial information. If patients do not qualify for the provided drug, they still may qualify for the cost-sharing program. If a patient does qualify, a 90-day supply is shipped to the doctor’s office for dispensing. Once qualified, there is no limit as to how long the patient can continue to receive the drug. For more information, contact Shire Roberts Inc. Patient Assistance Program, P.O. Box 698, Somerville, NJ 08876 (908-203-0657).

Nursing implications: Nurses evaluating the use of toremifene citrate should:

- Assess the menopausal status of patients with breast cancer. Therapy with antiestrogens in pregnant women may cause miscarriages, birth defects, and death of the fetus.
- Assess patients for history of thromboembolism and liver or renal insufficiency.
- Review patients’ current prescription and nonprescription medications, including vitamins and herbs.
- Assess patients for side effects (the most severe is thromboembolism).
- Conduct periodic monitoring of CBC, LFTs, and calcium level.

Patient education: Patients receiving toremifene citrate should be taught the following.

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