Fulvestrant Antiestrogen for Treatment of Breast Cancer

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In April 2002, the U.S. Food and Drug Administration (FDA) approved fulvestrant injection (Faslodex®, AstraZeneca Pharmaceuticals LP, Wilmington, DE) for the treatment of hormone receptor-positive, metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy (i.e., tamoxifen, Nolvadex® [AstraZeneca Pharmaceuticals LP]). Fulvestrant is the first in a new class of steroidal antiestrogens, the estrogen receptor downregulators. It targets and degrades the estrogen receptors in breast cancer cells and is the only antiestrogen that has demonstrated efficacy following tamoxifen failure (Bundred et al., 2002).

Clinical Trials

The efficacy of fulvestrant was demonstrated in clinical trials comparing the drug to the aromatase inhibitor anastrozole (Arimidex®, AstraZeneca Pharmaceuticals LP). Two randomized trials in North America and Europe were conducted in postmenopausal women with locally advanced or metastatic breast cancer. The double-blind, North American trial included 400 women, whereas the open, randomized, European trial included 451 women. All patients had progressed after previous therapy with an antiestrogen or progestin for breast cancer in the adjuvant or advanced disease setting. Subjects were randomized to receive either fulvestrant 250 mg intramuscularly once a month or anastrozole 1 mg orally each day.

Fulvestrant injection (Faslodex®, AstraZeneca Pharmaceuticals LP, Wilmington, DE) is a novel estrogen receptor antagonist with no known agonist effects. Indicated for the palliative treatment of postmenopausal, endocrine-responsive, advanced breast cancer, the drug is well tolerated, and its most common side effect is mild gastrointestinal symptoms. Fulvestrant is administered as a once-a-month intramuscular injection in an outpatient setting. Its unique mechanism of action represents a new way to palliate breast cancer and may offer new options for women with advanced, endocrine-responsive disease.

Key Words: breast neoplasms, estrogen antagonists

Dosage and Administration

The recommended dosage of fulvestrant is 250 mg intramuscularly at one-month intervals. It can be administered as either a single 5 ml injection or two 2.5 ml injections. Fulvestrant is supplied in 2.5 ml and 5 ml prefilled glass barrels. The syringes are presented in a tray with a polystyrene plunger rod and a safety needle (e.g., Safety Glide™, Becton Dickinson and Company, Franklin Lakes, NJ) for connection to the barrel.

Side-Effect Profile

In the North American and European clinical trials, the most common adverse events related to the use of fulvestrant were gastrointestinal symptoms (nausea 26% and 25.3%, vomiting 13% and 11.8%, constipation 12.5% and 10.6%, diarrhea 12.3% and 12.8%, abdominal pain 11.8% and 11.6%, respectively). Other reported side effects were headache, back pain, and injection site discomfort or irritation.

Vaginal bleeding has been reported (less than 1%) most commonly in patients during the first six weeks after changing from existing hormonal therapy to fulvestrant (AstraZeneca Pharmaceuticals LP, 2002).

This article originally appeared, in part, in the October 2002 issue of the Nurse Practitioner Special Interest Group Newsletter. Reprinted with permission. (Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Clinical Journal of Oncology Nursing or the Oncology Nursing Society.)