AURORA REMEDIES

ANASTROZOLE

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Anastrozole is an oral medication, indicated for adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer.

Chemical: Anastrozole
CAS Name: 2,2'-[5-(1H-1,2,4-Triazol-1-ylmethyl)-1,3-phenylene]bis(2-methylpropanenitrile)
Molecular Formula: C17H19N5
Molecular Weight: 293.37.

Prescription Medicine

CLINICAL PHARMACOLOGY

The growth of many cancers of the breast is stimulated or maintained by estrogens.
In postmenopausal women, estrogens are mainly derived from the action of the aromatase enzyme, which converts adrenal androgens (primarily androstenedione and testosterone) to estrone and estradiol. The suppression of estrogen biosynthesis in peripheral tissues and in the cancer tissue itself can therefore be achieved by specifically inhibiting the aromatase enzyme.
Anastrozole is a selective non-steroidal aromatase inhibitor. It significantly lowers serum estradiol concentrations and has no detectable effect on formation of adrenal corticosteroids or aldosterone.

INDICATIONS AND USAGE

Adjuvant Treatment
Anastrozole is indicated for adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer.
First-Line Treatment
Anastrozole is indicated for the first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor unknown locally advanced or metastatic breast cancer.
Second-Line Treatment
Anastrozole is indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. Patients with ER-negative disease and patients who did not respond to previous tamoxifen therapy rarely responded to anastrozole.

CONTRAINDICATIONS

Pregnancy And Premenopausal Women
Anastrozole may cause fetal harm when administered to a pregnant woman and offers no clinical benefit to premenopausal women with breast cancer. Anastrozole is contraindicated in women who are or may become pregnant. There are no adequate and well-controlled studies in pregnant women using Anastrozole. If Anastrozole is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus or potential risk for loss of the pregnancy.
Hypersensitivity
Anastrozole is contraindicated in any patient who has shown a hypersensitivity reaction to the drug or to any of the excipients. Observed reactions include anaphylaxis, angioedema, and urticaria.

PRECAUTIONS

Ischemic Cardiovascular Events
In women with pre-existing ischemic heart disease, an increased incidence of ischemic cardiovascular events was observed with anastrozole in the ATAC trial (17% of patients on anasrozole and 10% of patients on tamoxifen). Consider risk and benefits of anastrozole therapy in patients with pre-existing ischemic heart disease.
Bone Effects
Results from the ATAC trial bone substudy at 12 and 24 months demonstrated that patients receiving Anastrozole had a mean decrease in both lumbar spine and total hip bone mineral density (BMD) compared to baseline. Patients receiving tamoxifen had a mean increase in both lumbar spine and total hip BMD compared to baseline. Consider bone mineral density monitoring in patients treated with Anastrozole.
Cholesterol
During the ATAC trial, more patients receiving Anastrozole were reported to have elevated serum cholesterol compared to patients receiving tamoxifen (9% versus 3.5%, respectively).

ADVERSE REACTIONS

Serious adverse reactions with Anastrozole occurring in less than 1 in 10,000 patients, are:
1) skin reactions such as lesions, ulcers, or blisters;
2) allergic reactions with swelling of the face, lips, tongue, and/or throat. This may cause difficulty in swallowing and/or breathing;
3) changes in blood tests of the liver function, including inflammation of the liver with symptoms that may include a general feeling of not being well, with or without jaundice, liver pain or liver swelling.
Common adverse reactions (occurring with an incidence of ≥ 10%) in women taking Anastrozole included: hot flashes, asthenia, arthritis, pain, arthralgia, hypertension, depression, nausea and vomiting, rash, osteoporosis, fractures, back pain, insomnia, headache, bone pain, peripheral edema, increased cough, dyspnea, pharyngitis and lymphedema.
In the ATAC trial, the most common reported adverse reaction (> 0.1%) leading to discontinuation of therapy for both treatment groups was hot flashes, although there were fewer patients who discontinued therapy as a result of hot flashes in the Anastrozole group.
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

DOSAGE AND ADMINISTRATION

Recommended Dose
The dose of Anastrozole is one 1 mg tablet taken once a day. For patients with advanced breast cancer, anastrozole should be continued until tumor progression. Anastrozole can be taken with or without food.
For adjuvant treatment of early breast cancer in postmenopausal women, the optimal duration of therapy is unknown. In the ATAC trial, anastrozole was administered for five years.
No dosage adjustment is necessary for patients with renal impairment or for elderly patients.

STORAGE

Store at room temperature between 59-86 degrees Fahrenheit (15-30 degrees Celsius), away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

PRESENTATION:

1mg tablets in blister packs of 10 tablets – 5 blisters per box (50 tablets).

AURORA REMEDIES, SINGAPORE
www.aurora-remedies.com