



ANASTROZOLE

ANASTROZOLE 1 mg

Presented as box with 4 Blisters containing 15 capsules per carton

DESCRIPTION

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.

DOSAGE AND DIRECTIONS FOR USE

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.

PRESENTATION

1mg capsules in blister packs of 15 capsules — 4 blisters per box (60 capsules).

STORAGE

Store below 25°C. Store in the original package.