Aribex™ 1

Anastrozole USP

Jenphar
Bangladesh

جنفار
بنغلاديش

Composition:

Aribex™ 1 Tablet: Each film coated tablet contains Anastrozole USP 1 mg.

Pharmacology:

Anastrozole is a third-generation non-steroidal aromatase inhibitor. It inhibits the enzyme aromatase which is responsible for converting androgens to estrogens (aromatization). 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.

Indication:

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.

Dose & Administration:

The dose of Anastrozole is 1 mg tablet taken once daily. 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 recommended duration of treatment should be 5 years.

Contra-indications:

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.

Warnings and precautions:

Premenopausal women: Anastrozole offers no clinical benefit to premenopausal women with breast cancer.

Ischemic cardiovascular events: Caution should be exercised if Anastrozole is administered to women with pre-existing ischemic heart disease.

Decreases in bone mineral density may occur. Bone mineral density monitoring is required.

Increases in total cholesterol may occur. Cholesterol monitoring is required.

Side effects:

Common adverse reactions: 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.
Dermatologic: Skin reactions such as lesions, ulcers or blisters.
Allergic effects: Allergic reactions with swelling of the face, lips, tongue and/or throat. This may cause difficulty in swallowing and/or breathing.
Hematologic: Changes in blood tests of the liver function, including inflammation of the liver.

Use in Specific Populations:
Pregnancy: Pregnancy category X. Anastrozole can cause fetal abnormalities and risks, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.
Nursing mothers: It is not known whether Anastrozole is excreted into human milk or not. Caution should be exercised if Anastrozole is administered to women who are breast feeding.
Pediatric use: The safety and efficacy of Anastrozole has not been established in pediatric cases.
Geriatric Use: The pharmacokinetics of Anastrozole is not affected by age.
Renal impairment: The renal impairment does not influence the total body clearance. Dosage adjustment in patients with renal impairment is not necessary.
Hepatic impairment: Dosage adjustment is also not necessary in patients with stable hepatic cirrhosis. Anastrozole has not been studied in patients with severe hepatic impairment.

Drug Interaction:
Tamoxifen: Co-administration of Anastrozole and tamoxifen in breast cancer patients reduced Anastrozole plasma concentration by 27%. Tamoxifen should not be administered with Anastrozole.
Estrogen: Estrogen-containing therapies should not be used with Anastrozole.
Warfarin: Anastrozole doesn't alter the activity of both R- and S-warfarin.

Overdose:
There is no specific antidote to overdosage and treatment must be symptomatic. In the management of an overdose, consider that multiple agents may have been taken. Vomiting may be induced if the patient is alert. Dialysis may be helpful because anastrozole is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

Storage:
Store in a cool and dry place below 30°C, protect from light & moisture. Keep the medicine out of reach of children.

Packing:
Aribex™ 1 Tablet: Each box contains 3×10's tablets in Alu-Alu blister pack.

Manufactured for
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.
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