Arimidex®(Anastrozole 1mg)

Abbreviated Prescribing Information

COMPOSITION:

Each film-coated tablet contains: Anastrozole IP 1 mg

THERAPEUTIC INDICATIONS

Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.

Adjuvant treatment of early breast cancer in hormone receptor positive post-menopausal women who have received 2 to 3 years of adjuvant tamoxifen.

Treatment of advanced breast cancer in post-menopausal women.

POSOLOGY AND METHOD OF ADMINISTRATION

The recommended dose of Arimidex for adults including the elderly is one 1 mg tablet once a day. For postmenopausal women with hormone receptor-positive early invasive breast cancer,the recommended duration of adjuvant endocrine treatment is 5 years.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.

Pregnancy and lactation (Please refer to full prescribing information).

WARNINGS & PRECAUTIONS

Arimidex should not be used in premenopausal women. The menopause should be defined biochemically (luteinizing-hormone [LH], follicle stimulating hormone [FSH], and/or estradiol levels) in any patient where there is doubt about menopausal status.
Women with osteoporosis or at risk of osteoporosis, should have their bone mineral density formally assessed at the commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored.

FERTILITY, PREGNANCY AND LACTATION

- Pregnancy: Arimidex is contraindicated in pregnancy
- Breastfeeding : Arimidex is contraindicated in pregnancy
- Fertility: The effects of Arimidex on fertility in humans has not been studied.

UNDESIRABLE EFFECTS

The most frequently reported adverse reactions were headache, hot flushes, nausea, rash, arthralgia, joint stiffness, arthritis, and asthenia. Please refer to full prescribing information or detailed assessment of adverse events.

INTERACTIONS

Anastrozole inhibits CYPs 1A2, 2C8/9 and 3A4 in vitro. Clinical studies with antipyrine and warfarin showed that anastrozole at a 1 mg dose did not significantly inhibit the metabolism of antipyrine and R– and S-warfarin indicating the co-administration of Arimidex with other medicinal products is unlikely to result in clinically significant medicinal product interactions mediated by CYP enzymes. There were no clinically significant interactions with bisphosphonates.Co-administration of tamoxifen or estrogen-containing therapies with Arimidex should be avoided as this may diminish its pharmacological action

PHARMACOLOGICAL PROPERTIES

Mechanism of action

Arimidex is a potent and highly selective non-steroidal aromatase inhibitor.

Pharmacokinetic properties

Absorption of anastrozole is rapid and maximum plasma concentrations typically occur within two hours of dosing (under fasted conditions). Anastrozole is eliminated slowly with a plasma elimination half-life of 40 to 50 hours. Anastrozole is only 40% bound to plasma proteins. Metabolism of anastrozole occurs by N-dealkylation, hydroxylation and glucuronidation. The metabolites are excreted primarily via the urine.

To be sold by retail on the prescription of oncologist only

PHARMACEUTICAL PARTICULARS

Excipients

Lactose Monohydrate

Povidone

Sodium Starch Glycolate

Magnesium Stearate

Hypromellose

Macrogol 300

Titanium Dioxide

Shelf life

5 years

Storage

Do not store above 30°C and protect from moisture

Presentation

Each film-coated tablet contains: Anastrozole IP 1 mg

Arimidex® is a registered trademark of AstraZeneca group of companies.

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For more information, refer full prescribing information Version 6 dated 18th July 2012