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AVAILABLE ON REQUEST FROM ASTRAZENECA ON 1800 805 342 OR
www.astrazeneca.com.au/PI**

ARIMIDEX® (anastrozole) Minimum Product Information

INDICATIONS: *Early breast cancer:* Adjuvant treatment of early breast cancer in postmenopausal women with oestrogen/progesterone-receptor-positive disease. *Advanced breast cancer:* First line treatment of advanced breast cancer in postmenopausal women with oestrogen/progesterone-receptor-positive disease. Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. Patients with oestrogen-receptor-negative disease and patients who have not responded to previous tamoxifen therapy rarely respond to ARIMIDEX.

CONTRAINDICATIONS: Pregnancy (Category C), lactation, hypersensitivity to ingredients.

PRECAUTIONS: Not recommended for use in children or premenopausal women. Severe hepatic or renal impairment. Women with osteoporosis or at risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry at commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated and monitored as appropriate. No data available for use in combination with LHRH agonists. It is not known whether anastrozole impairs fertility in humans. Asthenia and somnolence reported – caution when driving or operating machinery while such symptoms persist.

INTERACTIONS: ARIMIDEX should not be co-administered with tamoxifen or oestrogen-containing therapies.

ADVERSE REACTIONS: *Very common* ($\geq 10\%$) – hot flushes, asthenia, arthralgia/joint stiffness, arthritis, headache, nausea, rash; *Common* ($\geq 1\%$ to $< 10\%$) – vaginal dryness/bleeding, hair thinning, allergic reactions, vomiting, diarrhoea, somnolence, Carpal Tunnel Syndrome, sensory disturbances (including paraesthesia, taste loss and taste perversion) increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, anorexia, hypercholesterolaemia, bone pain, myalgia; Others – see full PI.

DOSAGE AND ADMINISTRATION: One tablet (1 mg) orally once a day. For early breast cancer, the recommended total duration of hormonal therapy is 5 years. For patients being switched to ARIMIDEX from tamoxifen, the switch should occur after completion of 2 to 3 years of tamoxifen therapy. There are no data to support switching at earlier or later time points.

Date of approval: 15 June 2009. Date of most recent amendment: 16 May 2017