

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Arimidex™

COMPOSITION

Arimidex 1 mg film coated tablets (anastrozole)

INDICATIONS & USAGE

ARIMIDEX is indicated for adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. The effectiveness of ARIMIDEX in early breast cancer is based on an analysis of recurrence-free survival in patients treated for a median of 31 months. Further follow-up of study patients will be required to determine long-term outcomes.

Treatment of advanced breast cancer in post-menopausal women. Efficacy has not been demonstrated in oestrogen receptor negative patients unless they had a previous positive clinical response to tamoxifen.

PRESENTATION

Film-coated tablets containing 1 mg of anastrozole.

DOSAGE AND ADMINISTRATION

One 1mg tablet to be taken orally once a day

CONTRA-INDICATIONS

Pre-menopausal women, pregnant or lactating women, patients with severe renal impairment, patients with moderate or severe hepatic disease and patients with known hypersensitivity to anastrozole or to any of the excipients. Co-administration with oestrogen-containing therapies and concurrent tamoxifen therapy.

WARNINGS/PRECAUTIONS

Not recommended for use in children. Menopause should be defined biochemically in any patient where doubt about hormonal status. Care in driving or operating machinery. No data to support safety in patients with moderate or severe hepatic impairment or severe renal impairment. Women with osteoporosis or at risk of osteoporosis should have their bone mineral density assessed at the commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored. No information on use in combination with other anticancer drugs.

UNDESIRABLE EVENTS:

'Arimidex' is generally well tolerated. Pharmacologically predicted side-effects include hot flushes, vaginal dryness & hair thinning. Other adverse events include gastrointestinal disturbances (anorexia, nausea, vomiting, diarrhoea), asthenia, joint pain/stiffness, somnolence, headache or rash. Vaginal bleeding has been reported infrequently - evaluate further if it persists. Slight increase in total cholesterol. Hepatic enzyme changes and thromboembolic events, but no causal relationships established.

DRUG INTERACTIONS:

Co-administration of 'Arimidex' with other drugs (eg. antipyrine and cimetidine) is unlikely to result in clinically significant drug interactions mediated by cytochrome P450. A review of the clinical trial safety database did not reveal evidence of clinically significant interaction in patients treated with 'Arimidex' receiving other commonly prescribed drugs.

Consult full prescribing information before prescribing.

Further information is available on request.

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