(For the use only of a registered Medical Practitioner or a Hospital or a Laboratory)

Tamoxifen Tablets BP 10 mg

AEROTAMOX™

Composition:

Each film coated tablet contains:

Tamoxifen (As Tamoxifen Citrate) ..... 10 mg

Excipients ..... q.s.

Pharmacokinetics:

Peak plasma concentration of tamoxifen occur 4 to 7 hours after an oral dose. It is extensivelyprotein bound,plasma clearance is reported to bebiphasic and the terminal half-life may be longer than 7 days. It is extensively metabolised, themajor serum metabolite being N desmethyl tamoxifen.Several of the metabolites are stated to have similar pharmacologic activity to the parent compound. Tamoxifen is excreted slowly in the faeces,mainlyas conjugates. Small amounts are excreted in the urine. Tamoxifen appears to undergo enterohepatic circulation.

Indications:

Tamoxifen is indicated for the treatment of advanced breast cancer in postmenopausal women. Tamoxifen citrate is also used to stimulate ovulation in women with anovuatory infertility.

Dosage and Administration:

20 mg tablets daily, in 2 divided doses or as a single dose. Doses of up to 40mg daily may be given but no additional benefit has been demonstrated. Adjuvant therapy is normally continued for up to 5 years, although the optimum duration is still uncertain. To reduce breast cancer incidence in women at high risk of disease. Licensed dose of Tamoxifen is 20mg daily for 5 years. In the treatment of anovulatory infertility the usual dose is the equivalent of tamoxifen 20 mg daily on days 2,3,4 and 5 of the menstrual cycle, increased if necessary in subsequent cycles up to 80mg daily.In women with irregular menstruation the initial course may be begun on any day,and a second course begun at a higher dose after 45 days if there has been no responce. If the patients responds by menstruation, subsequent coures may begin on day 2 of the cycle.Or as prescribed by the physician.

Interaction

There is a risk of increased anticoagulant effect if tamoxifen is given concomitantly with coumarin anticoagulants.Conversely,concomitant use with cytotoxic drugs may increase the risk of thromboembolic events. Tamoxifen increase the dopaminergic effect of bromocriptine.

Precautions:

Tamoxifen should not be given during pregnancy and should be used with caution in women with functioning ovaries; the latter may also develop menstrual irregularities and cystic ovarian swelling.

Adverse Effects:

Tamoxifen is generally well tolerated, and the most frequent adverse effects are hot flushes and nausea and vomiting in up to 25% of patients .Other advers effects include oedema, vaginal bleeding or discharge,pruritus vulvae,rashes and dry skin,There may be an increased tendency to thrombo embolism,and pulmonary embolism and pulmonary embolism has occurred; alteration in the blood lipids have been reported,There have also been reports of dizziness, headache, depression, confusion, fatigue, hepatotoxicity & muscle cramp. Transient thrombocytopenia and leucopenia have been reported.blurred vision and loss of visual acuity,corneal opacities, and retinopathies have occurred.

Caution:

Foods,Drugs,Devices and Cosmetics Act prohibits dispensing without prescription.

Storage:

Store below 25°C. Protect from light.

Availability:

10 blister packs x 10 tablets (Box of 100's)

Número de registro.:

Código neutral: HP/Drugs/09/92

Manufactured for: Area Biotech Pvt Ltd.

Marketed and Exported By:

AREA IMPORTERS & EXPORTERS PVT. LTD.

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