Altamofen® Tablet 20mg

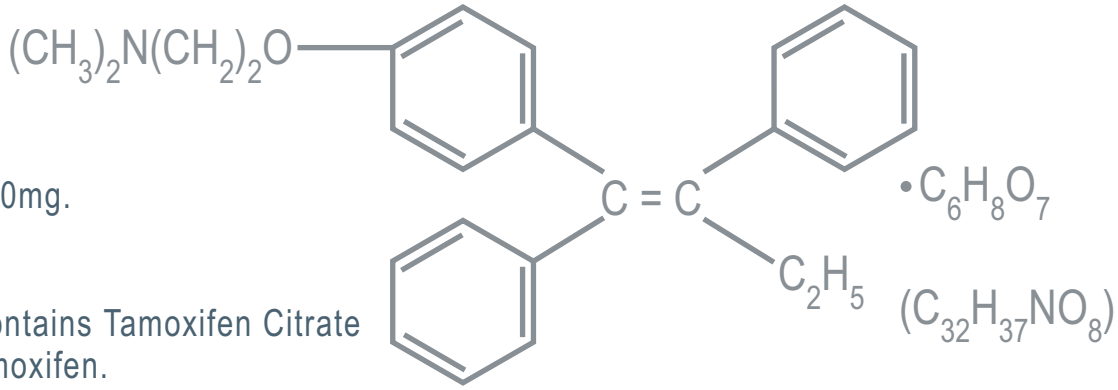
Alpha · Pharma
healthcare

GENERIC NAME:
Tamoxifen Citrate

CHEMICAL NAME:
(Z)2-[4-(1,2-diphenyl-1-butenyl)phenoxy]-N,N-dimethylethanamine 2-hydroxy-1,2,3-propanetricarboxylate.

MOLECULAR FORMULA:
$C_{32}H_{37}NO_8$

MOLECULAR WEIGHT:
563.62



DOSAGE FORM: Tablet -20mg.

COMPOSITION:
Each Altamofen® tablet contains Tamoxifen Citrate equivalent to 20 mg of Tamoxifen.

PHARMACOLOGICAL CLASSIFICATION:
Antioestrogen/Antineoplastic.

PHARMACOLOGICAL ACTION:
Altamofen® is a non steroidal antioestrogenic drug for oral administration. Chemically, Tamoxifen is the trans-isomer of a triphenylethylene derivative. It competes with estrogen for binding sites in the target tissues e.g. breast. When bound to the receptor, Tamoxifen induces changes in the receptor shape inhibiting its binding to the estrogen responsive element on DNA.

After oral administration Altamofen is readily absorbed with peak concentrations within 4 to 7 hours. Steady state concentration (about 300 ng/mL) can be achieved after 4 weeks of treatment with 40 mg daily. Altamofen is highly bound approximately 98% to plasma proteins.

Altamofen is metabolised predominantly to N-desmethyltamoxifen and to the minor metabolites, e.g. 4-hydroxytamoxifen. Altamofen has a half-life (t ½) of 7 days, and its metabolite N-desmethyltamoxifen has half-life is 14 days and both tamoxifen and/or its metabolites undergo extensive enterohepatic circulation which can be accountable for prolongation of serum levels and primary faecal excretion.

INDICATIONS:
Altamofen® tablet is indicated for the treatment of advanced breast cancer and adjuvant treatment of early breast cancer. In premenopausal women with metastatic breast cancer, Altamofen® is an alternative to oophorectomy or ovarian irradiation.

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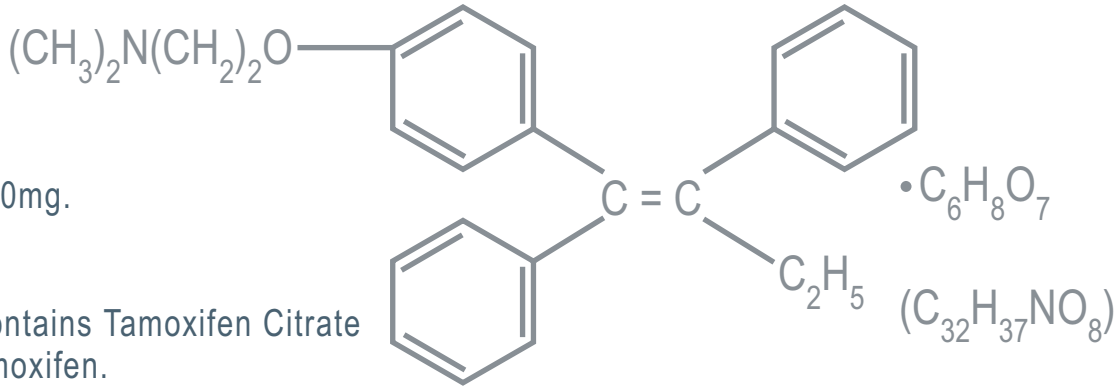

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DOSAGE AND ADMINISTRATION:
Oral Administration:
Initial Dose is 10 mg twice daily. If no response is obtained within one month, the dosage should be increased to 20 mg twice daily.
For patients with breast cancer, the recommended daily dose is 20-40 mg.
Dosages greater than 20 mg per day should be given in divided doses (morning and evening).

ADVERSE EFFECTS:
The following adverse effects were reported on oral administration:
Flushing, vomiting, increased bone and tumor pain, vaginal bleeding, menstrual irregularities, thrombocytopenia, leukopenia visual disturbances, Other adverse reactions which are seen in frequently are hypercalcemia associated with increased bone resorption, has been noted when patients with bony metastases commenced therapy, peripheral edema, distaste for food, pruritus vulvae, depression, dizziness, headache, hair thinning and/or partial hair loss, and vaginal dryness. Shortness of breath, swelling in legs, severe weakness.

CONTRA INDICATIONS:
- Altamofen® should not be used in patients with known hypersensitivity to drug or any one of the tablet excipients.
- Altamofen is contraindicated in infant, children, pregnancy and lactating mothers.

DRUG INTERACTIONS:
- Altamofen® potentiates the anticoagulant effect of warfarin, and this interaction can be life-threatening so monitoring of the patient's prothrombin time is recommended.

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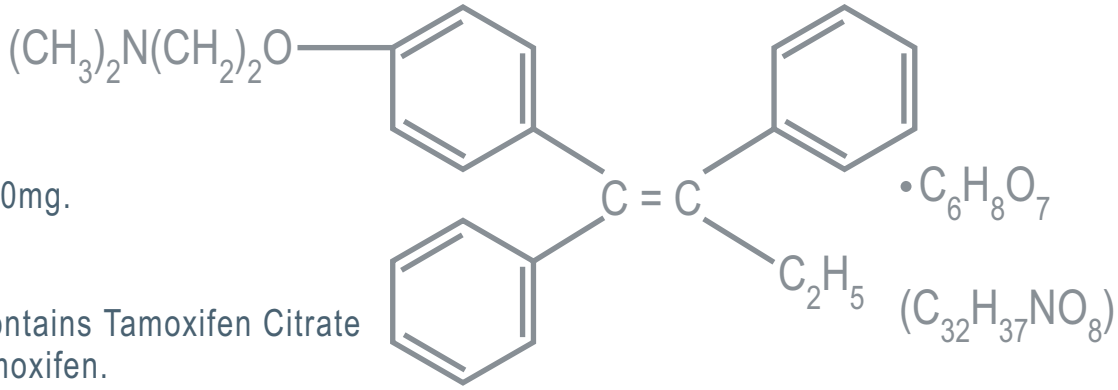

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DRUG INTERACTIONS: Contd..

- When cytotoxic agents are used in combination with Altamofen then there is an increased risk of thromboembolism.
- Altamofen® reduced letrozole plasma concentrations by 37%.
- Concurrent administration of Rifampicin or Aminogluthemide with Altamofen has been shown to be reduced plasma concentrations of tamoxifen and its metabolite, N-desmethyl tamoxifen.
- Concomitant Bromcriptine therapy has been shown to increased serum tamoxifen and N-desmethyl tamoxifen.

WARNING AND SPECIAL PRECAUTIONS:

- Endometrial changes:
  An increased incidence of endometrial changes, including hyperplasia, polyps and cancer ha been reported in association with tamoxifen treatment. Any patients receiving or having previously received tamoxifen, who report vaginal bleeding, should be promptly investigate.
- During treatment with this medicine, the following tests should be performed: Periodic complete blood count including platelet count, Liver function tests Urine function, serum cholesterol and triglycerides, calcium concentration in serum, and periodic gynecologic examinations.
- Use of this medicine may impair alertness, and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery, and any other activity requiring alertness.
- This medicine may cause particular sensitivity upon exposure to sun; therefore, avoid exposure to the sun and use appropriate protection (long clothing, hat, sunscreen agents, etc).

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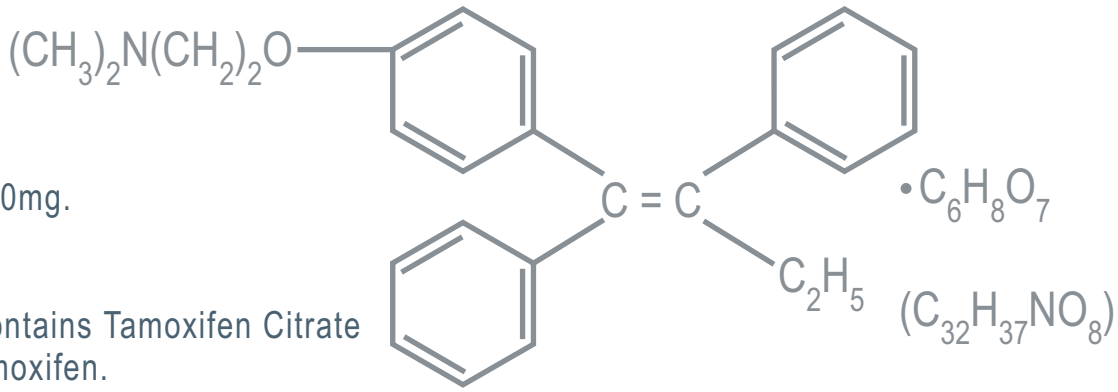

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IDENTIFICATION:
Altamofen® is a white coloured, round shaped tablet with a breaking line and "tmx" written on the flipside of the breaking line.

PRESENTATION:
A Strip of ten tablets in a blister. Such 10 blisters are packed in an individual carton with a leaflet.

STORAGE:
Store below 25°C, protect from light. Keep out of reach from children.

MARKETED BY
Alpha-Pharma Healthcare India Pvt. Ltd.
A-317, Sagar Tech Plaza
Sakinaka, Andheri-Kurla Road
Mumbai 400072
India

DATE OF PUBLICATION OF THIS PACKAGE INSERT
20th of August 2007