Tamoxifen:

Class:

- Antineoplastic Agent, Estrogen Receptor Antagonist; Selective Estrogen Receptor Modulator (SERM)

Indications:

- Treatment of metastatic (female and male) breast cancer;
- adjuvant treatment of breast cancer after primary treatment with surgery and radiation; reduce risk of invasive breast cancer in women with ductal carcinoma *in situ* (DCIS) after surgery and radiation;
- reduce the incidence of breast cancer in women at high risk

Unlabeled use :

- Treatment of mastalgia, gynecomastia, ovarian cancer, endometrial cancer, and desmoid tumors;
- risk reduction in women with Paget's disease of the breast (with ER-positive DCIS or without associated cancer);
- induction of ovulation;
- treatment of precocious puberty in females, secondary to McCune-Albright syndrome

Available dosage form in the hospital:

- 10 mg tablet
- 20 mg tablet

Trade Names:

Bilem , Citofen , Diemon , Fenahex , Genox , Ginarsan , Ginarsan Forte , Gynatam , Gyraxen , Kessar , Mamofen ,Medtax ,Moxafen , Neophedan ,Nolvadex , Nolvadex-D , Novofen , Novofen Forte , Novofen-D , Retaxim , **Soltamox** , Tadex , Tamec ,Tamifen ,Tamizam , Tamofen , Tamoplex , Tamorex ,Tamosin ,Tamoxi ,Tamoxifen-Eurogenerics ,Tamoxifen-Hexal ,Tamoxifen-ratioparm ,Tamoxifen-Teva ,Tamoxifen-Zeneca , Taxus ,Tecnofen , Xifen , Zitazonium.

Dosage: Note: For the treatment of breast cancer, patients receiving both tamoxifen and chemotherapy should receive treatment sequentially, with tamoxifen following completion of chemotherapy.

-**Breast cancer treatment:** Oral:

-*Adjuvant therapy (females):* 20 mg once daily for 5 years

- Premenopausal women: Duration of treatment is 5 years (Burstein, 2010; NCCN Breast Cancer guidelines v.2.2013)
- Postmenopausal women: Duration of tamoxifen treatment is 2-3 years followed by an aromatase inhibitor (AI) to complete 5 years; may take tamoxifen for the full 5 years (if contraindications or intolerance to AI) or extended therapy: 4.5-6 years of tamoxifen followed by 5 years of an AI (Burstein, 2010; NCCN Breast Cancer guidelines v.2.2013)
- ER-positive early breast cancer: Extended duration: Duration of treatment of 10 years demonstrated a reduced risk of recurrence and mortality (Davies, 2012)

-*Metastatic (males and females):* 20-40 mg daily (doses >20 mg should be given in 2 divided doses). **Note:** Although the FDA-approved labeling recommends dosing up to 40 mg daily, clinical benefit has not been demonstrated with doses above 20 mg daily (Bratherton, 1984).

-*Ductal carcinoma in situ (DCIS) (females), to reduce the risk for invasive breast cancer:* 20 mg once daily for 5 years

-**Breast cancer risk reduction (pre- and postmenopausal high-risk females):** Oral: 20 mg once daily for 5 years

-**Endometrial carcinoma, recurrent, metastatic, or high-risk (endometrioid histologies only) (unlabeled use):** Oral:

-*Monotherapy:* 20 mg twice daily until disease progression or unacceptable toxicity (Thigpen, 2001)

-*Combination therapy:* 20 mg twice daily for 3 weeks (alternating with megestrol acetate every 3 weeks); continue alternating until disease progression or unacceptable toxicity) (Fiorica, 2004)

-**Induction of ovulation (unlabeled use):** Oral: 20 mg once daily (range: 20-80 mg once daily) for 5 days (Steiner, 2005)

-**Ovarian cancer, advanced and/or recurrent (unlabeled use):** Oral: 20 mg twice daily (Hatch, 1991; Markman, 1996)

-**Paget's disease of the breast (risk reduction; with DCIS or without associated cancer):** Oral: 20 mg once daily for 5 years (NCCN Breast Cancer Guidelines, v.2.2013)

-**Dosage adjustment for DVT, pulmonary embolism, cerebrovascular accident, or prolonged immobilization:** Discontinue tamoxifen (NCCN Breast Cancer Risk Reduction Guidelines, v.1.2013)

Geriatric

Refer to adult dosing.

Renal Impairment:

No dosage adjustment provided in manufacturer's labeling.

Chronic dialysis: No dosage adjustment necessary (Janus, 2013).

Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling.

Common side effect:

- Cardiovascular: Vasodilation (41%), flushing (33%), hypertension (11%), peripheral edema (11%)
- Central nervous system: Mood changes (12% to 18%), pain (3% to 16%), depression (2% to 12%)
- Dermatologic: Skin changes (6% to 19%), rash (13%)
- Endocrine & metabolic: Hot flashes (3% to 80%), fluid retention (32%), altered menses (13% to 25%), amenorrhea (16%)
- Gastrointestinal: Nausea (5% to 26%), weight loss (23%), vomiting (12%)
- Genitourinary: Vaginal discharge (13% to 55%), vaginal bleeding (2% to 23%)
- Neuromuscular & skeletal: Weakness (18%), arthritis (14%), arthralgia (11%)
- Respiratory: Pharyngitis (14%)
- Miscellaneous: Lymphedema (11%)

Pregnancy Risk Factor: D