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:

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)


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