

Name(s)

- **Generic:** tamoxifen (ta MOKS I fen) | **Brand:** Soltamox

Therapeutic Category

- Selective Estrogen Receptor Modulator (SERM) | Antineoplastic Agent | Estrogen Receptor Antagonist

Dosage Form & Strength

- **Tablet:** 10 mg, 20 mg | **Solution:** 10 mg /5 mL (contains alcohol)

Indication(s)

1. **Breast Cancer (Risk Reduction):** Used to reduce the incidence of breast cancer in adult females that are considered at high risk for breast cancer.
2. **Breast Cancer (Treatment):** Adjuvant treatment for early stage estrogen receptor positive breast cancer in adult patients. Reduces the incidence of contralateral breast cancer. Tamoxifen reduces the risk of invasive breast cancer in patients following breast surgery and radiation (Ductal carcinoma in situ). The medication is also used in the treatment of metastatic breast cancer in estrogen receptor positive metastatic breast cancer.
3. **OFF LABEL** | Progressive or recurrent desmoid tumors; Recurrent metastatic high risk endometrial carcinoma; Gynecomastia; Idiopathic male infertility; Induction of ovulation in breast cancer patients; & Severe mastalgia; Advanced and/or recurrent ovarian cancer

Dosing by Indication

- Dosing for Adult Females for **Risk Reduction of Breast Cancer** in Pre- and Post-menopausal females at High Risk:
 - 20 mg po once daily for 5 years
- Dosing for Adult Females for **Treatment of Breast Cancer:**
 - **Adjuvant therapy:** 20 mg po once daily with the duration of therapy based on menopausal status. For example, in Pre- or Peri-menopausal endocrine therapy at initiation the duration is for 5 years. If the patient's menopausal status cannot be determined the tamoxifen may be continued for an additional 5 years for a total of 10 years. (May switch to an aromatase inhibitor for that additional 5 years). In Post-menopausal endocrine therapy initiation it is used for 10 years or tamoxifen for 5 years and followed by an aromatase inhibitor for 5 years.
 - **Ductal carcinoma in situ:** 20 mg po once daily for 5 years.
 - **Metastatic:** 20-40 mg po once daily. If 40 mg per day the dose is divided into two doses. It should be noted that doses >20 mg have not displayed any proven clinical benefits. In Pre-menopausal patients tamoxifen is offered as first-line therapy in patients with no prior endocrine therapy or if prior ovarian suppression through an aromatase inhibitor. In Post-menopausal patients tamoxifen is offered as second-line therapy if patients had no prior endocrine therapy.
- Dosing for various **OFF LABEL indications should be conducted only after referring to the most current literature.** Dosing is generally between 10-60 mg po 1-2 times daily with duration of therapy based on indications. 20 mg po bid appears to be a common dosing.

Mechanism of Action & Pharmacology

- **MOA/Pharmacology:** Tamoxifen selectively and competitively binds to estrogen receptor modulators on tumors. The complex that is produced leads to a decrease of DNA synthesis and an inhibition of the effects of estrogen. Tamoxifen is a nonsteroidal noncytotoxic agent that is considered cytostatic since the cells accumulate in the G0 and G1 phases.
- **Absorption:** Well absorbed | **Distribution** is wide to most tissues with a focus on tissues that inhibit estrogen receptors | **Metabolism:** Hepatically via the CYP2D6 and CYP3A4/5 pathways. Metabolites through both pathways creates substances



30 to 100 times more potent than tamoxifen itself. | **Excretion:** Approximately 65% excreted fecally and 30% in the urine | **Half-Life Elimination:** As tamoxifen ~5-7 days and as the metabolite (N-desmethyl tamoxifen) around 14 days. | Drug is highly **protein bound**

Special Populations & Considerations

- **Contraindications:** Concurrent warfarin therapy, Hx of DVTs (Deep Vein Thrombosis) or PEs (Pulmonary Embolisms)
- If patient is on **chemotherapy**, tamoxifen follows the completion of chemotherapy.
- Tamoxifen may induce **ovulation**.
- Tamoxifen may cause fetal harm during **pregnancy**; however long term effects on development have not been fully established.

Side Effects

- **General:** Hot flashes, headache, cramps, muscle/bone/back aches/pain, nausea, vomiting, constipation, diarrhea, anxiety
- **Most common:** flushing, vasodilation, fluid retention, weight loss

BLACK BOX WARNING: Uterine malignancies and thromboembolic events – serious and life-threatening events including uterine malignancies, stroke, pulmonary embolism.

Drug Interactions

- **General Cautions:** Anastrozole, letrozole, warfarin, estrogens, cimetidine, mitotane, SSRIs, carbamazepine
- **CYP2D6 inhibitors** may decrease formation of potent active metabolites and may reduce clinical effectiveness of tamoxifen.
- **CYP3A4 inducers** may decrease serum concentrations of the active metabolite and may reduce the clinical effectiveness of tamoxifen.
- **Letrozole** serum concentrations will be decreased by tamoxifen.

Monitoring Parameters

- Bone mineral density; Lipids; CYP2D6 metabolizer status; Complete Blood Count w/ platelets; Pregnancy; Ophthalmic exam; Abnormal vaginal bleeding; & Adherence

Patient Counseling Information

- Used to treat breast cancer or lower chances of getting breast cancer
- Can be used to treat a variety of other cancers and for other OFF LABEL uses
- Can be administered with or without food

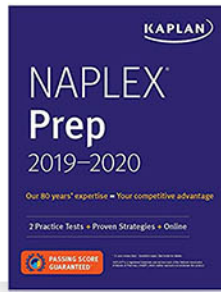
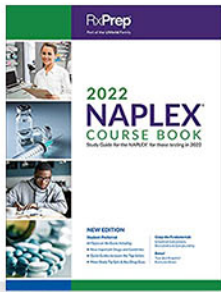
Reference(s)

- <https://www.drugs.com/ppa/tamoxifen.html>
- <https://www.webmd.com/drugs/2/drug-4497/tamoxifen-oral/details>

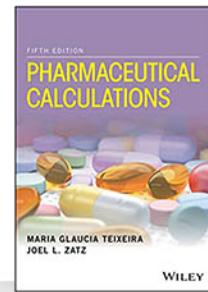
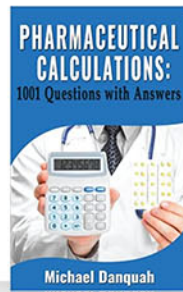
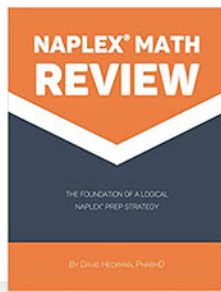
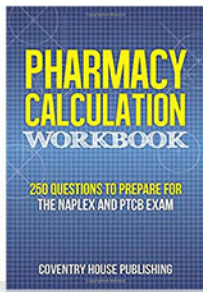


PREPARE FOR SUCCESS!

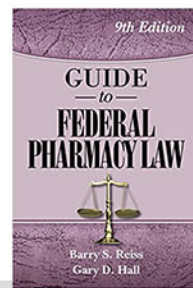
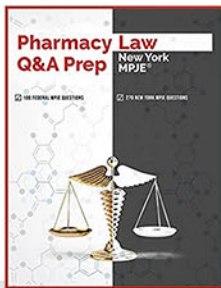
Comprehensive (NAPLEX)



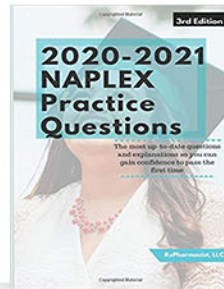
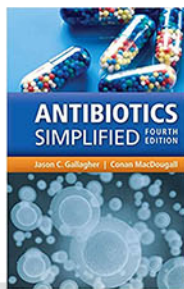
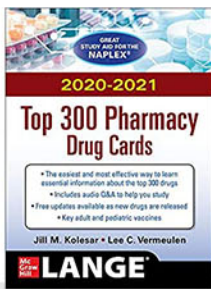
Calculations (NAPLEX)



Pharmacy Law (MPJE)



Supplemental



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When I was P1 one of the best pieces of advice I got from those before me was to use a NAPLEX Prep book while learning each topic.

This helps focus your learning and the repetition helps to retain info and indirectly prepare you for the NAPLEX



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