



Tamoxifen

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IMPORTANT WARNING:

Tamoxifen may cause cancer of the uterus (womb), strokes, and blood clots in the lungs. These conditions may be serious or fatal. Tell your doctor if you have ever had a blood clot in the lungs or legs, a stroke, or a heart attack. Also tell your doctor if you smoke, if you have high blood pressure or diabetes, if your ability to move around during your waking hours is limited, or if you are taking anticoagulants ('blood thinners') such as warfarin (Coumadin). If you experience any of the following symptoms during or after your treatment, call your doctor immediately: abnormal vaginal bleeding; irregular menstrual periods; changes in vaginal discharge, especially if the discharge becomes bloody, brown, or rusty; pain or pressure in the pelvis (the stomach area below the belly button); leg swelling or tenderness; chest pain; shortness of breath; coughing up blood; sudden weakness, tingling, or numbness in your face, arm, or leg, especially on one side of your body; sudden confusion; difficulty speaking or understanding; sudden difficulty seeing in one or both eyes; sudden difficulty walking; dizziness; loss of balance or coordination; or sudden severe headache.

Keep all appointments with your doctor. You will need to have gynecological examinations (examinations of the female organs) regularly to find early signs of cancer of the uterus.

If you are thinking about taking tamoxifen to reduce the chance that you will develop breast cancer, you should talk to your doctor about the risks and benefits of this treatment. You and your doctor will decide whether the possible benefit of tamoxifen treatment is worth the risks of taking the medication. If you need to take tamoxifen to treat breast cancer, the benefits of tamoxifen outweigh the risks.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with tamoxifen and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs>) or the manufacturer's website to obtain the Medication Guide.

About your treatment

Your doctor has prescribed tamoxifen for you. Tamoxifen comes as a tablet to take by mouth.

This medication is used to:

- treat breast cancer that has spread to other parts of the body in men and women.
- treat early breast cancer in women who have already been treated with surgery, radiation, and/or chemotherapy.
- reduce the risk of developing a more serious type of breast cancer in women who have had ductal carcinoma in situ (DCIS; a type of breast cancer that does not spread outside of the milk duct where it forms) and who have been treated with surgery and radiation.
- reduce the risk of breast cancer in women who are at high risk for the disease due to their age, personal medical history, and family medical history.

Tamoxifen is in a class of medications known as antiestrogens. It blocks the activity of estrogen (a female hormone) in the breast. This may stop the growth of some breast tumors that need estrogen to grow.

Tamoxifen is usually taken once or twice a day with or without food. Take tamoxifen at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain anything you do not understand. Take tamoxifen exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow tamoxifen tablets whole; do not split, chew, or crush them. Swallow the tablets with water or any other nonalcoholic drink.

If you are taking tamoxifen to prevent breast cancer, you will probably take it for five years. If you are taking tamoxifen to treat breast cancer, your doctor will decide how long your treatment will last. Do not stop taking tamoxifen without talking to your doctor.

If you forget to take a dose of tamoxifen, take the missed dose as soon as you remember it, and take your next dose as usual. However, if it is almost time for your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Other uses for this medicine

Tamoxifen is also used sometimes to induce ovulation (egg production) in women who do not produce eggs but wish to become pregnant. Tamoxifen is also sometimes used to treat McCune-Albright syndrome (a condition that may cause bone disease, early sexual development, and dark colored spots on the skin in children). Talk to your doctor about the possible risks of using this drug for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

Precautions

Before taking tamoxifen,

- tell your doctor and pharmacist if you are allergic to tamoxifen or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: aminoglutethimide (Cytadren); anastrozole (Arimidex), bromocriptine (Parlodel); cancer chemotherapy medication such as cyclophosphamide (Cytoxan, Neosar) letrozole (Femara); medroxyprogesterone (Depo-Provera, Provera, in Prempro); phenobarbital; and rifampin (Rifadin, Rimactane). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- in addition to the conditions listed in the IMPORTANT WARNING section, tell your doctor if you have or have ever had high blood levels of cholesterol.
- tell your doctor if you are pregnant or plan to become pregnant. You should not plan to become pregnant while taking tamoxifen or for 2 months after your treatment. Your doctor may perform a pregnancy test or tell you to begin your treatment during your menstrual period to be sure that you are not pregnant when you begin taking tamoxifen. You will

need to use a reliable nonhormonal method of birth control to prevent pregnancy while you are taking tamoxifen and for 2 months after your treatment. Talk to your doctor about the types of birth control that are right for you, and continue to use birth control even if you do not have regular menstrual periods during your treatment. Stop taking tamoxifen and call your doctor right away if you think you have become pregnant during your treatment. Tamoxifen may harm the fetus.

- tell your doctor if you are breast-feeding. You should not breastfeed during your treatment with tamoxifen.
- tell all of your doctors and other health care providers that you are taking tamoxifen.
- you will still need to look for early signs of breast cancer since it is possible to develop breast cancer even during treatment with tamoxifen. Talk to your doctor about how often you should examine your breasts yourself, have a doctor examine your breasts, and have mammograms (x-ray examinations of the breasts). Call your doctor right away if you find a new lump in your breast.

Side effects

Tamoxifen may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- increased bone or tumor pain
- pain or reddening around the tumor site
- hot flashes
- nausea
- excessive tiredness
- dizziness
- depression
- headache
- thinning of hair
- weight loss
- stomach cramps
- constipation
- loss of sexual desire or ability (in men)

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- vision problems
- loss of appetite
- yellowing of the skin or eyes
- unusual bruising or bleeding
- fever
- blisters
- rash
- swelling of the eyes, face, lips, tongue, throat, hands, arms, feet, ankles, or lower legs
- thirst
- muscle weakness
- restlessness

Tamoxifen may increase the risk that you will develop other cancers, including liver cancer. Talk to your doctor about this risk.

Tamoxifen may increase the risk that you will develop cataracts (clouding of the lens in the eye) that may need to be treated with surgery. Talk to your doctor about this risk.

Tamoxifen may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

Storage conditions

Keep tamoxifen in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- uncontrollable shaking of a part of the body
- unsteadiness
- dizziness

Special instructions

- Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to tamoxifen.
- Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking tamoxifen.
- Do not let anyone else take your medication. Talk to your pharmacist if you have any questions about refilling your prescription.

Brand names

- Nolvadex®

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