

Tamoxifen (ta-MOKS-i-fen)

Brand Name: Nolvadex[®] (nole-VA-dex)

Patient Education Quick Reference Guide

WARNING

For women taking tamoxifen to reduce the risk of developing breast cancer: Serious side effects have occurred in these patients, including uterine cancer, stroke and blood clots in the lung. If you are taking tamoxifen to reduce your risk of developing breast cancer, you should be sure to discuss the possible benefits versus the possible risks with your doctor or healthcare provider.

Uses For This Medication

- Tamoxifen is used to treat adults with breast cancer. It is also used to prevent breast cancer in adults who are at a high risk of developing the disease.
- This medication may also be given for other conditions as determined by your doctor.

How This Medication Works

Tamoxifen works by blocking the effects of estrogen, a hormone which causes some breast cancer cells to grow. When estrogen is blocked, the breast cancer cells, which need estrogen to grow, will not be able to grow.

Benefits of This Medication

Tamoxifen is used to treat breast cancer several different ways. It is used as an additional therapy after surgery for breast cancer, which is in the early stages. It can also be beneficial in the treatment of disease that has metastasized, or spread, to other parts of the body. Tamoxifen is also used to prevent the development of breast cancer in women who are at a high risk of developing the disease. Finally, tamoxifen has also been shown to prevent bone loss.

Who Should Not Take This Medication

You should **not** take this medication if you:

- Are allergic to tamoxifen or to any of its components
- Have a history of blood clots in the legs or lungs
- Are taking the medication warfarin (Coumadin[®])

NOTE: If you have a history of blood clots in the legs or lungs or are taking warfarin (Coumadin[®]), you should talk with your doctor or healthcare provider about whether tamoxifen is safe for you to take.

Precautions to be Aware of Before Taking This Medication

Blood related precautions

- Rarely, this medication may temporarily reduce the number of platelets in your blood. This can increase your risk of bleeding. Contact your doctor or healthcare provider if you notice unusual bleeding or bruising, have black or tar-like stools, see blood in your urine, or develop pinpoint red spots on your skin. If your platelet levels become too low, your doctor or healthcare provider may recommend that your treatment be delayed, that you receive a platelet transfusion, and/or that you take medication to help increase the number of platelets in your blood. To lower your chance of bleeding, do not use aspirin, aspirin-containing medications, or aspirin-like medications (for example ibuprofen, naproxen). Use caution with sharp objects like razors and nail cutters, and avoid activities that can cause cuts, bumps and bruises.

Organ related precautions

- Rarely, this medication can cause changes in the ability of your liver to work normally. In addition, this medication is broken down by enzymes (chemicals) in the liver and cleared from the body. In patients with severe liver disease, tamoxifen may not break down normally which can lead to high levels of this medication in the body and a greater chance of side effects. Your doctor or healthcare provider will check your liver regularly, usually through blood tests, while you are on this medication to make sure that your liver is working properly. If you have any liver problems before starting this medication, make sure that you tell your doctor or healthcare provider so that he or she can watch you carefully for possible problems or side effects.
- Rarely, this medication can increase the risk of eye problems, including the development of cataracts, scarring of the cornea, or changes in the retina, all of which can cause vision problems. If you experience any vision changes while on this medication, let your doctor or healthcare provider know.

Miscellaneous precautions

- This medication can increase the risk of uterine and endometrial cancer. You should talk with your doctor or healthcare provider about having regular pelvic examinations. If you experience symptoms of abnormal vaginal bleeding (for example, lasting longer than usual or bleeding between cycles), changes in menstruation, changes in vaginal discharge, pelvic pain or pressure, you should let your doctor or healthcare provider know immediately. If you have ever had surgery to remove your uterus, then you are not at an increased risk for these cancers.
- Rarely, blood clots have been reported in patients receiving tamoxifen. If you have ever had a blood clot, you should let your doctor or healthcare provider know. Contact your doctor or healthcare provider immediately if you experience pain or swelling in your leg(s) or if you experience sudden shortness of breath or difficulty breathing, sharp chest pain, sudden and severe headache, or pain that radiates down the shoulder and arm.
- Rarely, this medication can increase the risk of changes to the lining of the uterus which can lead to polyps, ovarian cysts, and changes in menstruation.
- This medication can cause a condition known as tumor flare during the first few weeks of treatment, especially in patients who have breast cancer which has metastasized, or spread, to the bone. Tumor flare is a syndrome which causes muscle pain and redness along with increased size of tumors. The size of these tumors will later decrease once this syndrome has subsided. Let your doctor or healthcare provider know if you are experiencing muscle pain and redness that do not get better.

Patient specific precautions

Pregnancy and breastfeeding precautions

- This medication may cause fetal harm. When taking this medication and for two months after stopping it, you should use effective birth control to prevent pregnancy. Tell your doctor or healthcare provider right away if you or your spouse/partner becomes pregnant.

Precautions (continued)

- You should not take hormonal birth control (pills, patches, rings, implants, injections) while on tamoxifen since this medication can stop hormonal birth control methods from working. Barrier type methods of birth control (condoms, diaphragms) should be used instead if needed.
- This medication has been reported to reduce a woman's ability to produce breast milk. It is not known whether this medication is found or excreted in breast milk. Since many medications are excreted in breast milk and because this medication can cause serious harmful reactions in infants, breastfeeding should be avoided.
- Many anti-cancer therapies can cause sterility. Notify your doctor or healthcare provider if you want to have children in the future.
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Medication and Food Interactions

Before using this medication, tell your doctor or healthcare provider of all prescription or over-the-counter products you are taking, including dietary supplements or vitamins, herbal medicines and homeopathic remedies. Do not start or stop any medication without your doctor or healthcare provider's approval. Possible interactions can occur with tamoxifen and the following foods or medications:

- Aminoglutethimide (Cytadren[®])
- Amiodarone (Cordarone[®])
- Barbiturates
- Birth control pills or other estrogen containing medications
- Bosentan (Tracleer[®])
- Carbamazepine
- Cyclosporine
- Delavirdine (Rescriptor[®])
- Diltiazem
- Efavirenz (Sustiva[®])
- Erythromycin
- Ethosuximide (Zarontin[®])
- Fosphenytin (Cerebyx[®])
- Grapefruit or grapefruit juice
- Imatinib mesylate (Gleevec[®])
- Ketoconazole (Nizoral[®])
- Letrozole (Femara[®])
- Mitomycin C (Mutamycin[®])
- Nevirapine (Viramune[®])
- Nifedipine
- Phenytoin (Dilantin[®])
- Phenobarbital
- Rifampin (Rifadin[®])
- Voriconazole (Vfend[®])
- Warfarin (Coumadin[®])

NOTE: This list may not include all medications that can have interactions with tamoxifen.

Side Effects

- All medications can cause side effects. However, not all patients will experience these side effects. In addition, other side effects not listed can also occur in some patients. You should call your doctor or healthcare provider if you have any questions or concerns while you are on this medication.
- You should contact your doctor or healthcare provider if you experience any side effect(s) which don't go away, worsen, are serious in nature, or are worrisome to you.
- Side effects can occur when tamoxifen is given alone or together with other chemotherapy medications. The side effects listed below are those reported in patients who were treated with tamoxifen alone.

More common side effects

- ✓ Hot flashes
- ✓ Vaginal discharge
- ✓ Temporary feeling of tiredness when starting tamoxifen therapy
- ✓ Water retention and weight gain

Less common side effects

Side Effects (continued)

- ✓ Irregular menstrual bleeding
- ✓ Changes in mood
- ✓ Increased bone and/or tumor pain shortly after starting treatment (see Precautions To Be Aware Of Before Taking This Medication)

Rare side effects

This is not a complete list of the rare side effects reported with tamoxifen. For a complete list, please talk with your doctor or healthcare provider about reviewing a copy of the package insert.

- ✓ Headache, dizziness
- ✓ Nausea, vomiting, loss of appetite, stomach cramps
- ✓ Visual changes or the development of cataracts (see Precautions To Be Aware Of Before Taking This Medication)
- ✓ Vaginal itching or dryness
- ✓ Rash
- ✓ Swelling/pain in hands or feet
- ✓ Chest pain
- ✓ Shortness of breath
- ✓ Blood clots in the veins or lungs (see Precautions To Be Aware Of Before Taking This Medication)
- ✓ Stroke (see Precautions To Be Aware Of Before Taking This Medication)
- ✓ Hair thinning
- ✓ Decreased platelet and/or white blood cell levels (see Precautions To Be Aware Of Before Taking This Medication)
- ✓ Increase in calcium blood level
- ✓ Liver problems including jaundice (yellowing of the skin and eyes) (see Precautions To Be Aware Of Before Taking This Medication)
- ✓ Changes in the lining of the uterus and/or uterine cancer (see Precautions To Be Aware Of Before Taking This Medication).

How To Take This Medication

- This medication is taken by mouth (orally) with or without food. Tamoxifen tablets are to be taken with water or another non-alcoholic liquid. Take this medication exactly as directed by your doctor or healthcare provider. If you do not understand these instructions, ask your doctor or healthcare provider to explain them to you. Tamoxifen is usually taken for five years.
- It is important that you only use this medication when it's been prescribed for you. Sharing this medication with someone for whom it is not prescribed could cause harm.
- If you miss a dose of tamoxifen, take it when you remember, then take the next dose as usual. If it is almost time for your next dose or you remember at your next dose, do not take extra tablets to make up the missed dose.
- If you accidentally take too many pills or someone else accidentally takes your medication, contact your doctor, your local poison control center at 1-800-222-1222, or emergency services immediately.

Proper Storage

- Store this medication at room temperature and keep in its original container.
- Keep this medication out of the reach of children or pets.
- Ask your doctor or healthcare provider how to dispose of any medication that you no longer use.

Notes

