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Tamoxifen: Patient drug information

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(For additional information <u>see "Tamoxifen: Drug information"</u> and <u>see "Tamoxifen: Pediatric drug information"</u>)

Brand Names: US Soltamox

Brand Names: Canada Apo-Tamox; Mylan-Tamoxifen; Nolvadex-D; PMS-Tamoxifen; Teva-

Tamoxifen

Warning

 This drug may raise the chance of very bad and sometimes deadly side effects like stroke, blood clots, or endometrial or uterine cancer.

What is this drug used for?

- · It is used to treat breast cancer.
- It is used to lower the chance of breast cancer in women with a higher chance of getting it. It may lower the chance of getting cancer in the other breast after one has cancer.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to tamoxifen or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have blood clots or have had blood clots in the past.
- If you are taking any of these drugs: Anastrozole or warfarin.
- If you are breast-feeding. Do not breast-feed while you take this drug.
 - This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Anemia, low white blood cell count, and low platelet count may rarely happen.
- This drug may raise the chance of getting cataracts or the need to have cataract surgery. Talk with the
 doctor.
- Be sure to have regular breast exams. Your doctor will tell you how often to have these. You will also need to do breast self-exams as your doctor has told you. Talk with your doctor.
- Women taking this drug need to be sure to have regular gynecology check-ups. Your doctor will tell you how often to have these. Talk with your doctor.
- This drug may stop you from having a period (menstrual bleeding) for some time. This is not a method of birth control.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- Use birth control that does not have hormones in it like a condom. Do this for as long as you take this drug and for 2 months after you stop taking it.
- If you get pregnant while taking this drug or within 2 months after your last dose, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high calcium levels like weakness, confusion, feeling tired, headache, upset stomach and throwing up, hard stools (constipation), or bone pain.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Change in eyesight.
- Any unexplained bruising or bleeding.
- A lump in the breast or breast soreness.
- · Low mood (depression).
- Feeling very tired or weak.
- · Fever or chills.
- · Sore throat.
- · Swelling.
- · Any skin change.
- · Very bad headache.

- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.
- Very bad and sometimes deadly liver problems have happened with this drug. Call your doctor right
 away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or
 stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- If you are a woman, call your doctor right away if you have pain when passing urine, pelvic pain or pressure, period (menstrual) changes like no period, vaginal bleeding that is not normal, or vaginal discharge.
- Some men have had sexual problems when taking this drug. These include lowered interest in sex and not able to get an erection. Call your doctor right away if you have sexual problems when taking this drug.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Hot flashes.
- · Upset stomach or throwing up.
- · Weight gain or loss.
- · Feeling tired or weak.
- · Back pain.
- · Bone pain.
- · Dizziness.
- Muscle or joint pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- · Take with or without food.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you are able to get pregnant, start taking this drug during your period (menstrual) cycle. You may need to have a pregnancy test before starting this drug. Talk with your doctor.

Tablet:

Swallow whole with some water or other drink.

Liquid:

· Only use the measuring device that comes with this liquid drug.

What do I do if I miss a dose?

- · Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

Tablet:

- Store at room temperature.
- · Protect from heat.

Liquid:

- Store at room temperature. Do not refrigerate or freeze.
- · Store in original container.
- Throw away any part not used after 3 months.

All products:

- · Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 11068 Version 117.0