

MEDICATION GUIDE

SOLTAMOX™ Oral Solution
(SOL-ta-mox)
Generic name: tamoxifen citrate

Written for women who use SOLTAMOX™ to lower their high chance of getting breast cancer or who have ductal carcinoma in situ (DCIS)

This Medication Guide discusses only the use of SOLTAMOX™ to lower the chance of getting breast cancer in high-risk women and in women treated for DCIS.

People taking SOLTAMOX™ **to treat** breast cancer have different benefits and different decisions to make than high-risk women or women with ductal carcinoma in situ (DCIS) taking SOLTAMOX™ to reduce the chance of getting breast cancer. If you already have breast cancer, talk with your doctor about how the benefits of treating breast cancer with SOLTAMOX™ compare to the risks that are described in this document.

Why should I read this Medication Guide?

This guide has information to help you decide whether to use SOLTAMOX™ to lower your chance of getting breast cancer.

You and your doctor should talk about whether the possible benefit of SOLTAMOX™ in lowering your high chance of getting breast cancer is greater than its possible risks. Your doctor has a special computer program or hand-held calculator to tell if you are in the high-risk group. If you have DCIS and have been treated with surgery and radiation therapy, your doctor may prescribe SOLTAMOX™ to decrease your chance of getting invasive (spreading) breast cancer.

Read this guide carefully before you start SOLTAMOX™. It is important to read the information you get each time you get more medicine. There may be something new. This guide does not tell you everything about SOLTAMOX™ and does **not** take the place of talking with your doctor. Only you and your doctor can determine if SOLTAMOX™ is right for you.

What is the most important information I should know about using SOLTAMOX™ to reduce the chance of getting breast cancer?

SOLTAMOX™ (tamoxifen citrate) is a prescription medicine that is like estrogen (female hormone) in some ways and different in other ways. In the breast, tamoxifen can block estrogen's effects. Because it does this, tamoxifen may block the growth of breast cancers that need estrogen to grow (cancers that are estrogen- or progesterone-receptor positive).

Tamoxifen citrate can lower the chance of getting breast cancer in women with a higher than normal chance of getting breast cancer in the next five years (high-risk women) and women with DCIS. **Because high-risk women don't have cancer yet, it is important to think carefully about whether the possible benefit of tamoxifen in lowering the chance of getting breast cancer is greater than its possible risks.**

This Medication Guide reviews the risks and benefits of using SOLTAMOX™ to reduce the chance of getting breast cancer in high-risk women and women with DCIS. This guide does not discuss the special benefits and decisions for people who already have breast cancer.

Why do women and men use SOLTAMOX™?

SOLTAMOX™ has more than one use. SOLTAMOX™ is used:

1. **to lower the chance** of getting breast cancer in women with a higher than normal chance of getting breast cancer in the next 5 years (high-risk women).
2. **to lower the chance** of getting invasive (spreading) breast cancer in women who had surgery and radiation for ductal carcinoma in situ (DCIS). DCIS means the cancer is only inside the milk ducts.
3. **to treat** breast cancer in women after they have finished early treatment. Early treatment can include surgery, radiation, and chemotherapy. Tamoxifen may keep the cancer from spreading to others parts of the body. It may also reduce the woman's chance of getting a new breast cancer.
4. in women and men, **to treat** breast cancer that has spread to other parts of the body (metastatic breast cancer).

This guide talks only about using SOLTAMOX™ to lower the chance of getting breast cancer (#1 and #2 above).

What are the benefits of SOLTAMOX™ to lower the chance of getting breast cancer in high-risk women and in women treated for DCIS?

A large US study looked at **high-risk women** and compared the ones who took tamoxifen for 5 years with others who took a pill without tamoxifen (placebo). High-risk women were defined as women who have a 1.7% or greater chance of getting breast cancer in the next 5 years, based on a special computer program. In this study:

- Out of every 1,000 high-risk women **who took a placebo**, each year about 7 got breast cancer.
- Out of every 1,000 high-risk women **who took tamoxifen**, each year about 4 got breast cancer.

The study showed that on average, high-risk women who took tamoxifen lowered their chances of getting breast cancer by 44%, from 7 in 1,000 to 4 in 1,000.

Another US study looked at **women with DCIS** and compared those who took tamoxifen for 5 years with others who took a placebo. In this study:

- Out of every 1,000 women with DCIS **who took placebo**, each year about 17 got breast cancer.
- Out of every 1,000 women with DCIS **who took tamoxifen**, each year about 10 got breast cancer.

The study showed that on average, women with DCIS who took tamoxifen lowered their chances of getting invasive (spreading) breast cancer by 43%, from 17 in 1,000 to 10 in 1,000.

These studies do not mean that taking SOLTAMOX™ will lower your personal chance of getting breast cancer. We do not know what the benefits will be for any one woman who takes SOLTAMOX™ to reduce her chance of getting breast cancer.

What are the risks of SOLTAMOX™?

In the studies described under "What are the benefits of SOLTAMOX™?", the high-risk women who took tamoxifen got certain side effects at a higher rate than those who took a placebo. **Some of these side effects can cause death.**

In one study, in women who still had their uterus

- Out of every 1,000 women who took a placebo, each year 1 got endometrial cancer (cancer of the lining of the uterus) and none got uterine sarcoma (cancer of the body of the uterus).
- Out of every 1,000 women who took tamoxifen, each year 2 got endometrial cancer and fewer than 1 got uterine sarcoma.

These results show that, on average, in high-risk women **who still had their uterus**, tamoxifen doubled the chance of getting endometrial cancer from 1 in 1,000 to 2 in 1,000, and it increased the chance of getting uterine sarcoma. **This does not mean that taking tamoxifen will double your personal chance of getting endometrial cancer or increase your chance of getting uterine sarcoma.** We do not know what this risk will be for any one woman. The risk is different for women who no longer have their uterus.

For all women in this study, taking tamoxifen increased the risk of having a blood clot in their lungs or veins, or of having a stroke. In some cases, women died from these effects.

Tamoxifen increased the risk of getting cataracts (clouding of the lens of the eye) or needing cataract surgery. (See "What are the possible side effects of SOLTAMOX™ for more details about side effects.)

What don't we know about taking SOLTAMOX™ to reduce the chance of getting breast cancer?

We don't know

- if tamoxifen lowers the chance of getting breast cancer in women who have abnormal breast cancer genes (BRCA1 and BRCA2)
- if taking tamoxifen for 5 years reduces the number of breast cancers a woman will get in her lifetime or if it only delays some breast cancers
- if tamoxifen helps a woman live longer
- the effects of taking tamoxifen with hormone replacement therapy (HRT), birth control pills, or androgens (male hormones)
- the benefits of taking tamoxifen if you are less than 35 years old

Studies are being done to learn more about the long-term benefits and risks of using tamoxifen to reduce the chance of getting breast cancer.

What are the possible side effects of SOLTAMOX™?

The most common side effect of tamoxifen is hot flashes. This is not a sign of a serious problem.

The next most common side effect is vaginal discharge. If the discharge is bloody, it could be a sign of a serious problem. [See "Changes in the lining (endometrium) or body of your uterus" below.]

Less common but serious side effects of tamoxifen are listed below. These can occur at any time. Call your doctor right away if you have any signs of side effects listed below:

- **Changes in the lining (endometrium) or body of your uterus.** These changes may mean serious problems are starting, including cancer of the uterus. The signs of changes in the uterus are:
 - Vaginal bleeding or bloody discharge that could be a rusty or brown color. You should call your doctor even if only a small amount of bleeding occurs.
 - Change in your monthly bleeding, such as in the amount or timing of bleeding or increased clotting.
 - Pain or pressure in your pelvis (below your belly button).
- **Blood clots in your veins or lungs.** These can cause serious problems, including death. You may get clots up to 2-3 months after you stop taking tamoxifen. The signs of blood clots are:
 - sudden chest pain, shortness of breath, coughing up blood
 - pain, tenderness, or swelling in one or both of your legs
- **Stroke.** Stroke can cause serious medical problems, including death. The signs of stroke are:
 - sudden weakness, tingling, or numbness in your face, arm or leg, especially on one side of your body
 - sudden confusion, trouble speaking or understanding
 - sudden trouble seeing in one or both eyes
 - sudden trouble walking, dizziness, loss of balance or coordination
 - sudden severe headache with no known cause
- **Cataracts or increased chance of needing cataract surgery.** The sign of these problems is slow blurring of your vision.
- **Liver problems, including jaundice.** The signs of liver problems include lack of appetite and yellowing of your skin or whites of your eyes.

Another less serious side effect that has been reported occasionally with SOLTAMOX™ is mild, temporary throat irritation. These are not all the possible side effects of tamoxifen. For a complete list, ask your doctor or pharmacist.

Who should not take SOLTAMOX™?

Do not take tamoxifen for any reason if you

- **Are pregnant or plan to become pregnant while taking tamoxifen or during the 2 months after you stop taking tamoxifen. Tamoxifen may harm your unborn baby.** It takes about 2 months to clear tamoxifen from your body. To be sure you are not pregnant, you can start taking tamoxifen while you are having your menstrual period. Or, you can take a pregnancy test to be sure you are not pregnant before you begin.
- **Are breast-feeding.** We do not know if tamoxifen can pass through your milk and harm your baby.
- **Have had an allergic reaction to tamoxifen or SOLTAMOX™** (the other name for tamoxifen), or to any of its inactive ingredients.

If you get pregnant while taking SOLTAMOX™, stop taking it right away and contact your doctor. SOLTAMOX™ may harm your unborn baby.

Do not take SOLTAMOX™ to lower your chance of getting breast cancer if

- You ever had a blood clot that needed medical treatment.
- You are taking medicines to thin your blood, like warfarin, (also called Coumadin®*).
- Your ability to move around is limited for most of your waking hours.
- You are at risk for blood clots. Your doctor can tell you if you are at high risk for blood clots.
- You do not have a higher than normal chance of getting breast cancer. Your doctor can tell you if you are a high-risk woman.

How should I take SOLTAMOX™?

- Take 2 tsp SOLTAMOX™ once or twice a day, as directed by your physician. You can take SOLTAMOX™ with or without food. Take your medicine every day. It may be easier to remember if you take it at the same time each day.
- If you forget a dose, 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 more than 2 tsp at one time to make up a missed dose.
- Take SOLTAMOX™ for 5 years, unless your doctor tells you otherwise.

What should I avoid while taking SOLTAMOX™?

- **Do not become pregnant while taking tamoxifen or for 2 months after you stop.** Tamoxifen can stop hormonal birth control methods from working. Hormonal methods include birth control pills, patches, injections, rings and implants. Therefore, while taking tamoxifen, **use birth control methods that**

don't use hormones, such as condoms, diaphragms with spermicide, or plain IUD's. If you get pregnant, stop taking tamoxifen right away and call your doctor.

- **Do not breast feed.** We do not know if tamoxifen can pass through your milk and if it can harm the baby.

What should I do while taking SOLTAMOX™?

- Have regular gynecology check-ups ("female exams"), breast exams and mammograms. Your doctor will tell you how often. These will check for signs of breast cancer and cancer of the endometrium (lining of the uterus). Because tamoxifen does not prevent all breast cancers, and you may get other types of cancers, you need these exams to find any cancers as early as possible.
- Because tamoxifen can cause serious side effects, pay close attention to your body. Signs you should look for are listed in "What are the possible side effects of SOLTAMOX™"
- Tell all of the doctors that you see that you are taking SOLTAMOX™.
- Tell your doctor right away if you have any new breast lumps.

General information about the safe and effective use of SOLTAMOX™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Your doctor has prescribed SOLTAMOX™ only for you. Do not give it to other people, even if they have a similar condition, because it may harm them. Do not use it for a condition for which it was not prescribed.

This Medication Guide is a summary of information about SOLTAMOX™ for women who use SOLTAMOX™ to lower their high chance of getting breast cancer or who have DCIS. If you want more information about SOLTAMOX™, ask your doctor or pharmacist. They can give you information about SOLTAMOX™ that is written for health professionals. For more information about SOLTAMOX™ or breast cancer, please visit www.savientpharma.com or call 1-866-692-6374.

Ingredients: tamoxifen, ethanol, glycerol, propylene glycol, sorbitol solution, licorice flavor, aniseed flavor, purified water.

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This Medication Guide has been approved by the U.S. Food and Drug Administration