

For the Patient: BRAJLDTAM

Other Names: Adjuvant Treatment of Resected Ductal Carcinoma in Situ using Tamoxifen

BR = BReast
AJ = AdJuvant
LD = Low Dose
TAM= TAMoxifen

ABOUT THIS MEDICATION

What is this drug used for?

When used to treat ductal carcinoma in situ (DCIS), tamoxifen reduces the chance of developing invasive breast cancer (cancer that has spread from its starting point into nearby healthy breast tissue), DCIS recurrence (DCIS that comes back after being removed by surgery), or contralateral breast cancer (cancer coming back in the other breast) by 50%.

How do these drugs work?

Tamoxifen (ta-MOX-i-fen) works by binding to estrogen (female hormone) receptors on breast cancer cells. For this reason, it is often called an "anti-estrogen" therapy, but you may also hear it referred to as "hormone therapy", or "hormone blocking therapy". Breast cancer cells can use estrogen to help them grow. Tamoxifen prevents this "growth stimulus" by binding to the cells where estrogen ordinarily would. In this way it can prevent microscopic numbers of cancer cells from surviving. Tamoxifen also works in other ways to prevent growth and survival of breast cancer cells. Tamoxifen is not helpful in preventing recurrences of breast cancers which do not have either estrogen or progesterone receptors (often referred to as ER and PR negative cancers). It is given only for cancers that express (or have) at least one kind of these receptors (ER positive and/or PR positive). It is a tablet that you take by mouth.

INTENDED BENEFITS

This therapy is being given to prevent breast cancer from developing, after a diagnosis of DCIS.

BRAJLDTAM TREATMENT SUMMARY

How is this drug given?

- Your treatment plan consists of tamoxifen, a tablet taken by mouth
- You will take one tablet of tamoxifen once every other day, for 3 years of treatment

The calendar below outlines your treatment plan:

| | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
|--------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Week 1 | tamoxifen | | tamoxifen | | tamoxifen | | tamoxifen |
| Week 2 | | tamoxifen | | tamoxifen | | tamoxifen | |
| Week 3 | tamoxifen | | tamoxifen | | tamoxifen | | tamoxifen |
| Week 4 | | tamoxifen | | tamoxifen | | tamoxifen | |

This will repeat for up to 3 years.

What other drugs can interact with BRAJLDTAM?

Other drugs such as warfarin (COUMADIN®) and rifampin (RIFADIN®, ROFACT®), and some antidepressants such as paroxetine (PAXIL®) may <u>interact</u> with tamoxifen. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your doses may need to be changed. Check with your doctor or pharmacist before you start taking any new drugs.

Other important things to know:

- Tell your doctor if you have ever had an unusual or allergic reaction to tamoxifen before taking tamoxifen.
- It is important to take tamoxifen exactly as directed by your doctor. Tamoxifen may
 be taken with food or on an empty stomach with a glass of water or juice. Tamoxifen
 may be taken at any time of the day but should be taken at the same time of the day
 on treatment days.
- If you **miss a dose** of tamoxifen, take it as soon as you can if it is within 24 hours of the missed dose. If it is over 24 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- Because tamoxifen works by blocking the effects of estrogen in your body, it is recommended that you avoid using estrogen replacement therapy such as conjugated estrogens (PREMARIN®, C.E.S.®, ESTRACE®, ESTRACOMB®, ESTRADERM® or, ESTRING®) or birth control pills. However, ESTRING® may be used in some cases to treat vaginal dryness as directed by your doctor.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of tamoxifen.

- Tamoxifen may harm the baby if used during pregnancy. At higher doses, tamoxifen
 is used as a fertility treatment. It is best to use a method of non-hormonal birth
 control while being treated with tamoxifen if you are able to become pregnant. Do
 not use birth control pills. Tell your doctor right away if you become pregnant. Do
 not breast feed during treatment.
- Tamoxifen will not induce menopause unless you are approaching the age of your natural menopause. It may cause your period to become irregular.
- **Tell** doctors or dentists that you are being treated with tamoxifen before you receive any treatment from them. If you are planning to have major surgery (e.g., joint replacement) you should stop taking tamoxifen 2-3 weeks prior to surgery and only restart it once you are back to normal activity, about 3 weeks after surgery. This helps to lower the risk of having a blood clot develop after surgery.
- **Store** tamoxifen tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- Tamoxifen is *usually well tolerated* and serious side effects are rare.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

| SIDE EFFECTS | MANAGEMENT |
|--|--|
| Hot flashes (sudden sweating and | If hot flashes are troublesome: |
| feelings of warmth) may commonly occur when you first start taking tamoxifen. This usually improves as your body adjusts to tamoxifen. | Take your tamoxifen at bedtime. |
| | If night sweats interfere with sleep, try taking tamoxifen in the morning. |
| | Some people find it helpful to avoid alcohol, spicy food, caffeine intake (coffee, tea, colas, chocolate). |
| | Follow a regular exercise program. |
| | Try staying in a cool environment. |
| | Wear layers so that if you do experience a hot flash, the outer layers may be removed. |
| | Ask your healthcare team for more advice if your hot flashes continue to bother you. There may be medications available. |

| SIDE EFFECTS | MANAGEMENT | | |
|---|---|--|--|
| Vaginal discharge or dryness may | If vaginal dryness is bothersome: | | |
| rarely occur. | Try a water based lubricant, such as REPLENS®. | | |
| | Ask your healthcare team for more advice if vaginal dryness continues to bother you. | | |
| | If vaginal discharge is bothersome make sure to mention it at your next visit. | | |
| Nausea (upset stomach) may sometimes | If nausea is a problem: | | |
| occur when you first start taking | ●Take your tamoxifen after eating. | | |
| tamoxifen. This should improve as your body adjusts to the tamoxifen. Most people have little or no nausea. | ●Try the ideas in <i>Practical Tips to Manage Nausea.</i> * | | |
| people have intie of he hadeed. | Tell your healthcare team if nausea continues. | | |
| Headache may sometimes occur. | Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. | | |
| Muscle or joint pain may sometimes occur. | You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity. | | |
| Skin rashes may rarely occur. | If itching is very irritating, call your healthcare team. Otherwise, be sure to mention it at your next visit. | | |
| Tiredness and lack of energy may sometimes occur. | This is usually mild. Do not drive a car or operate machinery if you are feeling tired. Try the ideas in Fatigue/Tiredness – | | |
| | Patient Handout.* | | |
| Swelling of hands, feet, or lower legs may rarely occur if your body retains | This is usually mild. If swelling is a problem: | | |
| extra fluid. | Elevate your feet when sitting. | | |
| | Avoid tight clothing. | | |
| High blood pressure may rarely occur with long-term use. | Check your blood pressure regularly. | | |

| SIDE EFFECTS | MANAGEMENT | |
|--|--|--|
| Blood clots may rarely occur. This is more likely to happen if you have had blood clots before. Signs to watch for include tenderness or hardness over a vein, calf tenderness, sudden onset of cough, chest pain, or shortness of breath. | Tell your doctor if you have ever had treatment for a blood clot. To help prevent blood clots: • Keep active. • Drink plenty of fluids. • Avoid tight clothing. • Do not sit with your legs crossed at the knees. | |
| Weight changes may sometimes occur. A small amount of weight gain or loss may occur. | To maintain your weight:Keep active.Modify your diet as necessary. | |
| Hair thinning may rarely occur. Your hair will grow back once you stop treatment with tamoxifen. Colour and texture may change. | To minimize thinning: Use a gentle shampoo and soft brush. Care should be taken with use of hair spray, bleaches, dyes, and perms. If hair loss is a problem, refer to Resources for Hair Loss and Appearance Changes – Patient Handout.* | |
| Changes in cholesterol or triglycerides (one of the types of fat in the blood) may rarely occur. | Tell your doctor if you have: A history of heart disease. High blood pressure. High cholesterol or triglycerides. You may need to have your cholesterol level checked a few months after starting tamoxifen. | |
| Endometrial cancer: cancer of the lining of the uterus (womb) may rarely occur with prolonged use of tamoxifen. | Tell your doctor if you have: • Any unexpected bleeding from the vagina, • Persistent abdominal pain, and/or • Pressure or discomfort in the pelvis. There is no risk of this cancer to women who have had a hysterectomy (uterus removed). | |
| Cataracts may rarely occur. | See an eye doctor if your vision becomes cloudy or blurred. | |

| SIDE EFFECTS | MANAGEMENT |
|-------------------------------------|---|
| Depression may rarely occur. | If you become unusually sad, or tearful, and lose interest in the usual things that give you pleasure, speak to your healthcare team. |

^{*} Please ask a member of your healthcare team for a copy.

STOP TAKING TAMOXIFEN AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain, or shortness of breath.
- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heartbeat, face swelling, or breathing problems.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Unexpected **bleeding** from the vagina, persistent **abdominal pain** and/or **pressure** or **discomfort** in the pelvis.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Changes in evesight.

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Uncontrolled nausea, vomiting, diarrhea, or constipation.
- Hot flashes that are troublesome.
- Significant persistent aches and pains.
- Headache or pain not controlled with acetaminophen.
- Excessive swelling of hands, feet or lower legs.
- Trouble sleeping.
- Vaginal discomfort, dryness, discharge.
- Significant weight gain or loss.
- Excessive breast swelling or soreness.
- Cough or sore throat that doesn't go away.
- Skin rash or itching.
- Feelings of depression or anxiety (nervousness or worry) that is not usual for you.
- Dizziness

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact _____ at telephone number _____.