

## **For the Patient: PROTOCOL SMTAM**

Other Names: Palliative Therapy for Malignant Melanoma  
Using Tamoxifen

**SM = Melanoma**

**TAM = Tamoxifen**

### **ABOUT THIS MEDICATION**

#### **What is this drug used for?**

- Tamoxifen(ta-MOX-i-fen) is a drug that is used to treat many types of cancers including breast cancer and melanoma.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to tamoxifen before taking tamoxifen.

#### **How does this drug work?**

- Tamoxifen blocks the effect of estrogen produced by your body and decreases the growth of hormone sensitive tumours. Tamoxifen also have anti-cancer effects not related to the hormone estrogen. Tamoxifen kills cancer cells by inducing cell death. How tamoxifen works in melanoma treatment is not clearly understood.

### **INTENDED BENEFITS**

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body. It may improve your current symptoms, and delay or prevent the onset of new ones.

### **TREATMENT SUMMARY**

#### **How is this drug given?**

- Tamoxifen is a tablet taken by mouth twice a day continuously.

#### **What will happen when I get my drug?**

- Your very first appointment for this treatment will take longer than other appointments because a pharmacist will be reviewing the possible side effects of tamoxifen and how to manage them. It is a good idea to bring someone with you to your first appointment for this treatment.

- Tamoxifen may harm the baby if used during pregnancy. At higher doses, tamoxifen is used as a fertility treatment. Although you are close to menopause, tamoxifen may induce ovulation and you may be able to become pregnant. It is best to **use a method of birth control** while being treated with tamoxifen if you are able to become pregnant. **Do not use birth control pills.** Barrier forms of contraception are recommended. 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.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

### Are there any risks?

- Tamoxifen is **usually well tolerated** and serious side effects are rare.
- Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

SIDE EFFECTS	How common is it?	MANAGEMENT
<b>Hot flashes</b> (sudden sweating and feelings of warmth) may commonly occur when you first start taking tamoxifen. This usually improves as your body adjusts to tamoxifen.	Very Common	<p>If hot flashes are troublesome:</p> <ul style="list-style-type: none"> <li>• Take your tamoxifen at bedtime.</li> <li>• If night sweats interfere with sleep, try taking tamoxifen in the morning.</li> <li>• Some people find it helpful to avoid alcohol, spicy food, caffeine intake (coffee, tea, colas, chocolate).</li> <li>• Follow a regular exercise program.</li> <li>• Try staying in a cool environment.</li> <li>• Wear layers so that if you do experience a hot flash, the outer layers may be removed.</li> <li>• Talk to your doctor if your hot flashes continue to bother you. There may be medications available to lessen them.</li> </ul>
<b>Vaginal discharge or dryness</b> may rarely occur.	Rare	<p>If vaginal dryness is bothersome:</p> <ul style="list-style-type: none"> <li>• Try a water based lubricants, such as REPLENS®.</li> <li>• Ask your doctor for more advice if vaginal dryness continues to bother you.</li> </ul> <p>If vaginal discharge is bothersome make sure to mention it at your next visit.</p>

SIDE EFFECTS	How common is it?	MANAGEMENT
<b>Nausea</b> (upset stomach) may sometimes occur <b>when you first start</b> taking tamoxifen. This should improve as your body adjusts to the tamoxifen. Most people have little or no nausea.	Uncommon	If nausea is a problem: <ul style="list-style-type: none"> <li>• Take your tamoxifen after eating.</li> <li>• Try the ideas in <i>Food Choices to Control Nausea</i>.*</li> </ul>
<b>Headache</b> may sometimes occur.	Uncommon	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
<b>Muscle or joint pain</b> may sometimes occur.	Uncommon	You may take acetaminophen (e.g., TYLENOL®) or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
<b>Skin rashes</b> may rarely occur.	Rare	If the rash is bothersome: <ul style="list-style-type: none"> <li>• Call your doctor during office hours.</li> <li>• Otherwise make sure to mention it at your next visit.</li> </ul>
<b>Tiredness</b> and lack of energy may sometimes occur.	Uncommon	<ul style="list-style-type: none"> <li>• This is usually mild. If it persists:</li> <li>• Try the ideas in <i>Your Bank of Energy Savings: How People with Cancer Can Handle Fatigue</i>.*</li> </ul>
<b>Swelling</b> of hands, feet, or lower legs may rarely occur if your body retains extra fluid.	Rare	This is usually mild. If swelling is a problem: <ul style="list-style-type: none"> <li>• Elevate your feet when sitting.</li> <li>• Avoid tight clothing.</li> </ul>
<b>High blood pressure</b> may rarely occur with long-term use.	Rare	Check your blood pressure regularly.

SIDE EFFECTS	How common is it?	MANAGEMENT
<p><b>Blood clots</b> may rarely occur, usually in the leg. 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.</p>	<p>Rare</p>	<p>Tell your doctor if you have ever had treatment for a blood clot.</p> <p>To help prevent blood clots:</p> <ul style="list-style-type: none"> <li>• Keep active.</li> <li>• Drink plenty of fluids.</li> <li>• Avoid tight clothing.</li> <li>• Do not sit with your legs crossed at the knees for long periods of time.</li> </ul>
<p><b>Weight changes</b> may sometimes occur. A small amount of weight gain or loss may occur.</p>	<p>Uncommon</p>	<p>To maintain your weight:</p> <ul style="list-style-type: none"> <li>• Keep active.</li> <li>• Modify your diet as necessary.</li> </ul>
<p><b>Hair thinning</b> may rarely occur. Your hair will grow back once you stop treatment with tamoxifen. Colour and texture may change.</p>	<p>Rare</p>	<p>To minimize thinning:</p> <ul style="list-style-type: none"> <li>• Use a gentle shampoo and soft brush.</li> <li>• Care should be taken with use of hair spray, bleaches, dyes, and perms.</li> </ul>
<p><b>Changes in cholesterol or triglycerides</b> may rarely occur.</p>	<p>Rare</p>	<p>Discuss this with your doctor if you have:</p> <ul style="list-style-type: none"> <li>• A history of heart disease. High blood pressure.</li> <li>• Elevated triglycerides.</li> <li>• You may need to have your cholesterol and triglycerides level checked a few months after starting tamoxifen.</li> </ul>

SIDE EFFECTS	How common is it?	MANAGEMENT
<b>Endometrial cancer:</b> cancer of the lining of the uterus (womb) may rarely occur with prolonged use of tamoxifen.	Rare	Tell your doctor if you have: <ul style="list-style-type: none"> <li>• any unexpected bleeding from the vagina, persistent abdominal pain and/or pressure or discomfort in the pelvis.</li> </ul> There is no risk of this cancer to women who have had a hysterectomy (uterus removed).
<b>Cataracts</b> may rarely occur.	Rare	See an eye doctor if your vision becomes cloudy or blurred.
<b>Depression</b> may rarely occur.	Rare	If you become unusually sad, or tearful, and lose interest in the usual things that give you pleasure, speak to your doctor.

## **INSTRUCTIONS FOR THE PATIENT**

### **How should I store this drug?**

- **Store** tamoxifen tablets out of the reach of children, at room temperature, away from heat, light and moisture.

### **How should I use this drug?**

- Tamoxifen may be taken with food or on an empty stomach with a glass of water or juice. Tamoxifen may be taken any time of the day but should be taken around the same time each day. Take tamoxifen at **evenly spaced times** during the day.
- If you **miss a dose** of tamoxifen, take it as soon as you can. Take the rest of the day's dose at your usual time. If you remember at the time for the next dose, take both doses and return to your usual dosing times.

### **What other drugs can interact with Tamoxifen?**

- Other drugs such as warfarin(COUMADIN®) and rifampin(RIFADIN®, ROFACT®) and some antidepressants such as paroxetine(PAXIL®) may **interact** with tamoxifen. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start taking any new drugs.
- Because tamoxifen blocks the effect of estrogen produced by your body and decreases the growth of hormone sensitive tumours, 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.

**THE FOLLOWING INFORMATION IS VERY IMPORTANT**

**STOP TAKING TAMOXIFEN AND SEE YOUR DOCTOR 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** including dizziness, fast heart beat, face and tongue swelling, and breathing problems with or without a rash.

**SEE YOUR DOCTOR 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 eyesight.**

**CHECK WITH YOUR DOCTOR 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(Tylenol®) or ibuprofen(ADVIL®).
- Excessive swelling of hands, feet or lower legs.
- Trouble sleeping.
- Vaginal discomfort, dryness, or discharge.
- Significant weight gain or loss.
- Persistent cough or sore throat.
- Skin rash or itching.
- Depression, anxiety (nervousness or worry) or dizziness that is not usual for you.

**If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:**

\_\_\_\_\_ at telephone number: \_\_\_\_\_