

# Tamoxifen Lupin Tablets

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Tamoxifen Lupin?

Tamoxifen Lupin contains the active ingredient Tamoxifen. Tamoxifen Lupin is used to treat breast cancer or reduce the risk of breast cancer occurring if you are at increased risk of breast cancer.

For more information, see Section [1. Why am I using Tamoxifen Lupin?](#) in the full CMI.

### 2. What should I know before I use Tamoxifen Lupin?

Do not use if you have ever had an allergic reaction to Tamoxifen Lupin or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Tamoxifen Lupin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Tamoxifen Lupin and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Tamoxifen Lupin

- The usual starting dose is 20 mg once a day. Your doctor may increase this dose to 40 mg a day, depending on your condition and how you respond to the medicine. Swallow the tablets with a glass of water. Do not chew or crush the tablets.

More instructions can be found in Section [4. How do I use Tamoxifen Lupin?](#) in the full CMI.

### 5. What should I know while using Tamoxifen Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Tamoxifen Lupin.</li><li>Use effective contraception (birth control) to avoid becoming pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not take Tamoxifen Lupin to treat any other complaints unless your doctor tells you to.</li><li>Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>You must not get pregnant while you are taking Tamoxifen Lupin tablets.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how Tamoxifen Lupin affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Not relevant</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store in a cool dry place where the temperature stays below 25°C.</li><li>Keep the tablets away from moisture, heat or sunlight</li></ul>

For more information, see Section [5. What should I know while using Tamoxifen Lupin?](#) in the full CMI.

### 6. Are there any side effects?

More common side effects include hot flushes, night sweats, nausea, vomiting, unusual vaginal discharge or dryness and menstrual irregularities or for premenopausal women, periods stopping, any changes in your period, itching around the genital area, diarrhoea, stomach pain or constipation, headache, dizziness or light headedness, fluid retention, numbness or pins and needles sensation in the hands or feet, changes in taste, tiredness, depression, hair thinning or hair loss, leg cramps, aching muscles, sudden onset of weakness or paralysis of the arms or legs.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Tamoxifen Lupin

Active ingredient(s): Tamoxifen

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tamoxifen Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tamoxifen Lupin.**

**Where to find information in this leaflet:**

- [1. Why am I using Tamoxifen Lupin?](#)
- [2. What should I know before I use Tamoxifen Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Tamoxifen Lupin?](#)
- [5. What should I know while using Tamoxifen Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Tamoxifen Lupin?

**Tamoxifen Lupin contains the active ingredient**

**Tamoxifen.** Tamoxifen belongs to a class of medicines commonly known as anti-oestrogen. It works by blocking the actions of oestrogen. Oestrogen is a natural female sex hormone. In some types of breast cancer, oestrogen can help cancer cells to grow.

**Tamoxifen Lupin is used to** treat breast cancer or reduce the risk of breast cancer occurring if you are at increased risk of breast cancer. If you and your healthcare professional are considering using Tamoxifen Lupin for reducing the risk of breast cancer occurring, your knowledge of treatment risks becomes more important because you don't currently have breast cancer. Tamoxifen Lupin therapy may be uncommonly associated with serious side effects such as deep vein thrombosis (DVT - blood clots in veins of your leg), pulmonary embolus (blood clots in your lungs) and uterine cancer. In some women, these events were fatal. Less serious side effects such as hot flushes, vaginal discharge, menstrual irregularities and gynaecological conditions may also occur. Whether the benefits of treatment outweigh the risks depends on your age, health history, your level of breast cancer risk and on your personal judgement. Tamoxifen Lupin therapy to reduce the risk of breast cancer may not be appropriate for all women at increased risk for breast cancer. An assessment with your healthcare professional of the potential benefits and risks prior to starting therapy for reduction in breast cancer risk is essential. You should understand that Tamoxifen Lupin reduces, but does not eliminate, the risk of breast cancer.

## 2. What should I know before I use Tamoxifen Lupin?

### Warnings

**Do not take Tamoxifen Lupin if:**

- you are allergic to tamoxifen, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- if you are pregnant or plan to become pregnant.
- the expiry date printed on the packaging has passed.
- the packaging is torn or shows signs of tampering

**Some of the symptoms of an allergic reaction may include:**

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take Tamoxifen Lupin for reducing the risk of breast cancer occurrence if:**

- you are taking medicines used to prevent blood clots such as warfarin
- you have had deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).

**Check with your doctor if you:**

- are taking any other anti-oestrogen medicines. Their use is not recommended
- if you have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- have not been through menopause
- smoke. It may increase your risk of serious side effects.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Tamoxifen Lupin should not be used during pregnancy or breastfeeding. A small number of unwanted complications, such as birth defects, have been reported in the unborn baby of women who have taken this medicine. However, it has not been shown whether these were due to Tamoxifen Lupin.

## Birth Control

If sexually active, your doctor may suggest you use a nonhormonal form of contraception while you are taking Tamoxifen Lupin and for two months after you have stopped treatment with it.

## Tell your doctor if you have or have had any of the following medical conditions

- Liver problems
- any blood disorder or problems such as thrombocytopenia or leucopenia
- unusual or unexplained vaginal bleeding or discharge
- deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your legs)

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### Some medicines may interfere with Tamoxifen Lupin and affect how it works. These include:

- oral contraceptives ('the pill')
- hormone replacement therapy
- other medicines used to treat cancer, including chemotherapy
- medicines used to prevent blood clots such as warfarin and heparin
- rifampicin, an antibiotic
- antidepressants such as paroxetine or fluoxetine
- aromatase inhibitors (hormone therapy) such as anastrozole, letrozole or exemestane.

These medicines may be affected by Tamoxifen Lupin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are taking any other anti-coagulant medicines, you may require further monitoring by your doctor.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tamoxifen Lupin.**

**Your doctor may consider your treatment carefully if you are taking any of these medicines.**

## 4. How do I take Tamoxifen Lupin?

### How much to take

- Your doctor will decide how much Tamoxifen Lupin you need to take.
- The usual starting dose is 20 mg once a day. Your doctor may increase this dose to 40 mg a day, depending on your condition and how you respond to the medicine.

### How to take Tamoxifen Lupin

- Swallow the tablets with a glass of water. Do not crush or chew the tablets.
- Tamoxifen Lupin can be taken with or without food.
- Keep taking Tamoxifen Lupin for as long as your doctor recommends.

### When to take Tamoxifen Lupin

Take your medicine at about the same time each day.

### If you forget to take Tamoxifen Lupin

If you miss your dose at the usual time take it as soon as you remember, as long as it is 12 hours before the next dose is due.

If it is less than 12 hours to the next dose, do not take the dose you have missed.

**Do not take a double dose to make up for the dose that you missed.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### If you take too much Tamoxifen Lupin

If you think that you have used too much Tamoxifen Lupin, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

There have been reports of heart rhythm problems associated with an overdose of this medicine.

## 5. What should I know while using Tamoxifen Lupin?

### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Tamoxifen Lupin.
- **Visit your doctor regularly and keep all of your appointments, so that your progress can be checked.**
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Use birth control to avoid becoming pregnant.

Tamoxifen Lupin should be stopped 3 weeks before undergoing surgery to reduce the risk of blood clots or other complications.

If you go into hospital, let the medical staff know that you are taking Tamoxifen Lupin.

Tell your doctor immediately if you become pregnant while taking Tamoxifen Lupin, or within two months of stopping treatment.

Tell your doctor immediately if you notice any unusual gynaecological symptoms, especially vaginal bleeding or discharge, even if it occurs after treatment with Tamoxifen Lupin has stopped.

Unusual bleeding or discharge from the vagina are possible side effects of Tamoxifen Lupin but they may also be symptoms of uterine or endometrial cancer. These along with other changes to the uterus lining (endometrium) have been reported in association with the use of this medicine.

You will need to have regular gynaecological check-ups while you are taking Tamoxifen Lupin. Your doctor may also order regular blood tests to check your calcium levels, white blood cell and platelet counts.

### Things you should not do

- Do not take Tamoxifen Lupin to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- You must not get pregnant while you are taking Tamoxifen Lupin tablets. Ask your doctor about reliable methods of contraception while you are taking this medication.

### Things to be careful of

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Tamoxifen Lupin affects you.**

Tamoxifen Lupin may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

#### Drinking alcohol

Tell your doctor if you drink alcohol.

#### Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Keep the tablets away from light.

Do not store Tamoxifen Lupin or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

#### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Skin/soft tissue problems:</b> <ul style="list-style-type: none"><li>• lumps anywhere in the body</li><li>• yellowing of the skin or eyes, dark coloured urine</li><li>• sensitivity to the sun</li><li>• unexplained bruising</li></ul> <b>General well-being:</b> <ul style="list-style-type: none"><li>• excessive thirst</li></ul> <b>Visual problems:</b> <ul style="list-style-type: none"><li>• any changes or disturbances in your vision</li></ul> <b>Bone problems</b>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>unusual pain or pressure around your pelvis, in your bones or anywhere in your body</li> <li>pain and reddening around the tumour or bone pain</li> </ul> <p><b>Infections</b></p> <ul style="list-style-type: none"> <li>frequent infection, fever, severe chills, sore throat or mouth ulcers</li> </ul> <p><b>Blood or circulation problems</b></p> <ul style="list-style-type: none"> <li>swelling of the hands, ankles and feet</li> <li>unusual tiredness, shortness of breath and dizziness when exercising, and looking pale</li> </ul>	
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<p><b>Bone problems:</b></p> <ul style="list-style-type: none"> <li>Tamoxifen Lupin may decrease bone density in premenopausal women. It is not known if this increases the risk of fractures. Ask your doctor for advice about ways to maintain your bone health.</li> </ul> <p><b>Vaginal problems:</b></p> <ul style="list-style-type: none"> <li>If you have any unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure) when you are taking Tamoxifen Lupin or anytime afterwards, tell your doctor. This is because a number of changes to the lining of the womb (endometrium) may occur, some of which may be serious and could include cancer.</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> <li>swelling of the face, lips, tongue and/or throat</li> <li>wheezing with difficulty breathing.</li> <li>rash, itching or hives</li> </ul> <p><b>Tummy problems:</b></p> <ul style="list-style-type: none"> <li>severe abdominal pain, loss of appetite, nausea, vomiting, and fever</li> </ul> <p><b>Vision problems:</b></p> <ul style="list-style-type: none"> <li>Cases of cataracts have been observed in some patients. Optic nerve diseases have been reported in patients receiving tamoxifen and, in a small number of cases, blindness has occurred.</li> </ul> <p><b>Blood or circulation problems:</b></p> <ul style="list-style-type: none"> <li>Increased risk of blood clots or blockages in the arteries and cardiovascular events with chest pain. Ovarian cysts (in premenopausal women) have also occurred with tamoxifen.</li> </ul> <p><b>Infections:</b></p> <ul style="list-style-type: none"> <li>Cough and shortness of breath due to a condition known as interstitial pneumonitis have also been reported.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Tamoxifen Lupin contains

<b>Active ingredient (main ingredient)</b>	20 mg of tamoxifen (as citrate)
<b>Other ingredients (inactive ingredients)</b>	maize starch lactose monohydrate povidone (K30) magnesium stearate brilliant scarlet 4R.
<b>Potential allergens</b>	Sugars as lactose monohydrate

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Tamoxifen Lupin looks like**

Tamoxifen Lupin tablets are pink, round and biconvex.

Each pack contains 30 or 60 tablets.

## **Who distributes Tamoxifen Lupin**

### **Southern Cross Pharma Pty Ltd**

Suite 2, Level 2

19-23 Prospect Street

Box Hill, Vic 3128

Email: [ghinfo@generichealth.com.au](mailto:ghinfo@generichealth.com.au)

Phone: +61 3 9809 7900

Website: [www.generichealth.com.au](http://www.generichealth.com.au)

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