

Tamoxifen Sandoz®

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 Sandoz?

Tamoxifen Sandoz contains the active ingredient tamoxifen citrate. Tamoxifen Sandoz is used to either 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 Sandoz?](#) in the full CMI.

2. What should I know before I use Tamoxifen Sandoz?

Do not use if you have ever had an allergic reaction to tamoxifen citrate 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 Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tamoxifen Sandoz 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 Sandoz?

- The usual dose is 20 mg of Tamoxifen Sandoz each day. This is two 10 mg Tamoxifen Sandoz tablets taken together or one 20 mg Tamoxifen Sandoz tablet taken once a day. Some people need to take 40 mg once a day.
- **Swallow your Tamoxifen Sandoz tablets whole, with a full glass of water. Do not chew or crush the tablets.**

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

5. What should I know while using Tamoxifen Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Tamoxifen Sandoz.• Be sure to keep all your appointments with your doctor so your progress can be checked.• If you go into hospital, please let the medical staff know that you are taking Tamoxifen Sandoz.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Tamoxifen Sandoz, or lower the dosage, unless you have discussed this with your doctor.• Do not take Tamoxifen Sandoz to treat any other complaints unless your doctor tells you to.• Do not get pregnant while you are taking Tamoxifen Sandoz and for nine months after you stop taking Tamoxifen Sandoz.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Tamoxifen Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Tamoxifen Sandoz tablets in the blister pack until it is time to take them.• Keep it in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some may be minor and temporary. However, some side effects may be serious. Tell your doctor immediately if you have a skin rash, itching, hives or peeling skin, swelling of the face, lips, tongue and/or throat, difficulty in swallowing or breathing (angioedema), wheezing with difficulty breathing, sudden onset of weakness or paralysis of the arms or legs, sudden difficulty with speaking, walking, difficulty in holding things or difficulty in thinking, any of which may occur because the blood supply in the blood vessels of the brain is reduced.

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 Sandoz®

Active ingredient(s): *tamoxifen citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tamoxifen Sandoz. **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 Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Tamoxifen Sandoz?

Tamoxifen Sandoz contains the active ingredient tamoxifen citrate. Tamoxifen Sandoz blocks the actions of estrogen. Estrogen is a natural female sex hormone. In some types of breast cancer, estrogen can help cancer cells to grow.

Tamoxifen Sandoz is used to either 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 Sandoz 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 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 Sandoz therapy to reduce the risk of breast cancer may not be appropriate for all women at increased risk of 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 Sandoz reduces, but does not eliminate, the risk of breast cancer.

Your doctor may prescribe this medicine for another use. Tamoxifen Sandoz is not addictive.

2. What should I know before I use Tamoxifen Sandoz?

Warnings

Do not use Tamoxifen Sandoz if:

- you are allergic to tamoxifen citrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to other anti-estrogen medicines
- you are allergic to any other medicines or substances, such as foods, preservatives or dyes. If you have an allergic reaction, you may experience a skin rash, hay fever, difficulty breathing or feel faint.
- 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:

- have any other medical conditions such as:
 - a history of hereditary angioedema (as Tamoxifen Sandoz may cause or worsen symptoms of hereditary angioedema)
 - any unexplained vaginal bleeding
 - problems with your blood
 - liver problems
 - deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs)
 - any heart conditions including heart rhythm problems (arrhythmia). The risk of heart rhythm problems may be increased in such patients when using Tamoxifen Sandoz.It may not be safe for you to take Tamoxifen Sandoz if you have any of these conditions.
- take any medicines for any other condition.

If you are a premenopausal woman taking Tamoxifen Sandoz for reduction of breast cancer risk or for breast cancer treatment, loss of the mineral content of bones may occur.

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

Do not use Tamoxifen Sandoz if you are pregnant, trying to become pregnant or are breastfeeding.

We do not know if it is safe for you to take it while you are pregnant. It may affect your baby if you take it at any time during pregnancy.

Your baby may take in Tamoxifen Sandoz from breast milk if you are breastfeeding

Children

Do not give Tamoxifen Sandoz to children.

There is no experience of its use in children.

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.

Tell your doctor if you are taking:

- oral contraceptives ('the pill')
- hormone replacement therapy
- medicines used to thin your blood e.g. warfarin
- rifampicin
- chemotherapy
- any medicines that you buy at the chemist, supermarket or health food shop.

Tamoxifen Sandoz should not be taken with aromatase inhibitors such as anastrozole, letrozole or exemestane.

These medicines may affect the way Tamoxifen Sandoz works or may not work as well. They could also cause side effects if you take them with Tamoxifen Sandoz.

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 Sandoz.

4. How do I use Tamoxifen Sandoz?

How much to take

- Your doctor will decide how much Tamoxifen Sandoz you need to take.
- The usual dose is 20 mg of Tamoxifen Sandoz each day. This is two 10 mg Tamoxifen Sandoz tablets taken together or one 20 mg Tamoxifen Sandoz-tablet taken once a day.
- Some people need to take 40 mg once a day. Your doctor will tell you if this is necessary.
- **Swallow your Tamoxifen Sandoz whole, with a full glass of water. Do not chew or crush the tablets.**

When to take Tamoxifen Sandoz

- **Take Tamoxifen Sandoz at about the same time each day.**
- It does not matter if you take Tamoxifen Sandoz before, with or after food.

How to long to take Tamoxifen Sandoz

- Continue taking Tamoxifen Sandoz for as long as your doctor or pharmacist tells you to.

If you forget to use Tamoxifen Sandoz

Tamoxifen Sandoz should be used regularly at the same time each day. 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, skip the dose you missed and take your next dose when you are meant to.

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

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

If you use too much Tamoxifen Sandoz

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

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), 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.

If you take too much Tamoxifen Sandoz you may experience problems with the rhythm of your heart.

5. What should I know while using Tamoxifen Sandoz?

Things you should do

- **Be sure to keep all your appointments with your doctor so your progress can be checked**
- **Tell any other doctors, dentists and pharmacists who are treating you that you are taking Tamoxifen Sandoz**
- **If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Tamoxifen Sandoz**
- **If you go into hospital, please let the medical staff know that you are taking Tamoxifen Sandoz.**

Remind any doctor, dentist or pharmacist you visit that you are using Tamoxifen Sandoz.

Things you should not do

- **Do not get pregnant while you are taking Tamoxifen Sandoz and for nine months after you stop taking Tamoxifen Sandoz.** Ask your doctor about reliable methods of contraception.
- **Do not breastfeed while you are taking Tamoxifen Sandoz.**
- **Do not take Tamoxifen Sandoz to treat any other complaints unless your doctor tells you to.**

- Do not stop taking Tamoxifen Sandoz, or lower the dosage, unless you have discussed this with your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take Tamoxifen Sandoz if the packaging is torn or shows signs of tampering.

Driving or using machines

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

Some patients may experience dizziness, fatigue or light headedness.

Looking after your medicine

- Keep your Tamoxifen Sandoz tablets in the blister pack until it is time to take them. If you take Tamoxifen Sandoz out of the blister pack it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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.

It may have no effect at all, or worse, an entirely unexpected effect if you take it 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.

Tamoxifen Sandoz helps most people with breast cancer, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tamoxifen Sandoz.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • depression • hot flushes • nausea and vomiting • unusual vaginal discharge 	<p>Speak to your doctor if you have any of these less</p>

<ul style="list-style-type: none"> • any change in your periods • itching around the vagina • diarrhoea or constipation • headache, dizziness or light headedness • hair thinning or hair loss • leg cramps 	<p>serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • unusual pain or pressure around your pelvis, in your bones or anywhere in your body • excessive thirst • swelling of the hands, ankles and feet • any changes in your vision • pain and reddening around the tumour • lumps anywhere in the body • unusual tiredness, shortness of breath and dizziness when exercising, and looking pale • frequent infection, fever, severe chills, sore throat or mouth ulcers • unexplained bruising • yellowing of the skin or eyes, dark coloured urine • disturbances of vision 	<p>Tell your doctor as soon as possible if you experience any of the following symptoms</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • skin rash, itching, hives or peeling skin • swelling of the face, lips, tongue and/or throat, difficulty in swallowing or breathing (angioedema) • wheezing with difficulty breathing • sudden onset of weakness or paralysis of the arms or legs, sudden difficulty with speaking, walking, difficulty in holding things or difficulty in thinking, any of which may occur because the blood supply in the blood vessels of the brain is reduced. These symptoms could be signs of a stroke. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effect.</p>

Very serious side effects are rare.

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.

Cases of optic nerve diseases have been reported in patients receiving tamoxifen and, in a small number of cases, blindness has occurred.

If you have an unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure) when you are taking Tamoxifen Sandoz 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.

Tamoxifen Sandoz 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.

Tamoxifen Sandoz may cause or worsen symptoms of hereditary angioedema.

Increased risk of blood clots and ovarian cysts (in premenopausal women) have been seen with tamoxifen.

Rarely an increased level of triglycerides (increased levels of fats in the blood) sometimes with pancreatitis (pain or tenderness in the upper abdomen) has been seen with tamoxifen.

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 or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Sandoz contains

Active ingredient (main ingredient)	tamoxifen citrate
Other ingredients (inactive ingredients)	lactose monohydrate sodium starch glycollate povidone microcrystalline cellulose magnesium stearate titanium dioxide hypromellose macrogol 4000
Potential allergens	lactose

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

What Tamoxifen Sandoz looks like

Tamoxifen Sandoz 10 mg – white, round, biconvex, film coated tablets (Aust R 80056).

Tamoxifen Sandoz 20 mg – white, round, biconvex, film coated tablets with a notch on one side (Aust R 80076).

Available in blisters of 30 and 60 tablets.

Not all strengths and pack sizes may be available in Australia and New Zealand.

Who distributes Tamoxifen Sandoz

Tamoxifen Sandoz is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Tamoxifen Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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