

TAMOXIFEN SANDOZ®

tamoxifen citrate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tamoxifen Sandoz. It does not contain all the information that is known about Tamoxifen Sandoz.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tamoxifen Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tamoxifen Sandoz is used for

Tamoxifen Sandoz is used to treat breast cancer.

It contains the active ingredient tamoxifen citrate. Tamoxifen citrate is an anti-oestrogen which blocks the effect of oestrogen. Oestrogen is a natural female sex hormone.

In some types of breast cancer, oestrogen can help cancer cells to grow. By blocking its effect Tamoxifen Sandoz stops or slows the growth of cancer cells.

Your doctor will have explained why you are being treated with Tamoxifen Sandoz and told you what dose to take.

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

Your doctor may have prescribed Tamoxifen Sandoz for another reason. Ask your doctor if you have any questions about why this medicine was prescribed for you.

There is no evidence that Tamoxifen Sandoz is addictive.

Before you take Tamoxifen Sandoz

When you must not take it

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.

Discuss contraception with your doctor.

Although Tamoxifen Sandoz blocks female hormones, it is not a contraceptive.

Tamoxifen Sandoz should not be used during pregnancy as birth defects can result. A nine month interval is recommended between stopping treatment and becoming pregnant.

Your baby may be taking in Tamoxifen Sandoz from breast milk if you are breastfeeding.

Do not use Tamoxifen Sandoz if you are allergic to tamoxifen or any of the other ingredients in Tamoxifen Sandoz.

Do not give Tamoxifen Sandoz to children.

There is no experience of its use in children.

Do not take after the used by (expiry) date printed on the pack.

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

Do not take Tamoxifen Sandoz if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you have any allergies to:**
 - tamoxifen, the active ingredient in Tamoxifen Sandoz
 - any of the other ingredients in Tamoxifen Sandoz listed at the end of this leaflet
 - other anti-oestrogen medicines
 - any other medicines
 - any other substances, including foods, preservatives or dyes.

If you have an allergic reaction, you may experience a skin rash, hayfever, difficulty breathing or feel faint.

- you have or ever had any of these medical conditions:**

- any blood disorders or problems, such as low white blood cell counts (leukopenia) or low platelet counts (thrombocytopenia)
- any liver problems, such as hepatitis
- unusual or any unexplained vaginal bleeding or discharge
- deep vein thrombosis (DVT – blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).

Taking other medicines

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

In particular, tell your doctor if you take any of the following:

- oral contraceptive ('the pill')
- hormone replacement therapy
- anticoagulants, such as warfarin and phenindione, used to reduce blood clotting
- chemotherapy
- rifampicin, an antibiotic used to treat tuberculosis (TB)
- paroxetine, fluoxetine (e.g. antidepressants)
- bupropion (antidepressant or aid to smoking cessation)
- quinidine (for example used in the treatment of cardiac arrhythmia)
- cinacalcet (for treatment of disorders of the parathyroid gland).

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

These medicines may be affected by Tamoxifen Sandoz, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking Tamoxifen Sandoz.

How to take Tamoxifen Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide how much Tamoxifen Sandoz you have to take.

The usual recommended dose for adults is 20 mg once daily (one Tamoxifen Sandoz 20 mg tablet or two Tamoxifen Sandoz 10 mg tablets).

Doses may be increased to 40 mg daily.

Tamoxifen Sandoz is not approved for use in children.

How to take it

Swallow Tamoxifen Sandoz tablets whole with a glass of water. Do not chew or crush the tablets.

When to take it

Take this medicine about the same time each day.

It does not matter if you take it before, with or after food.

How long to take it

The duration of treatment will be determined for your specific condition by your doctor.

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

If you forget to take your dose

Take your dose as soon as you remember, as long as it is 12 hours before the next dose is due, and continue to take it as you would normally.

If it is almost time for your 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Tamoxifen Sandoz. 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.

While you are using Tamoxifen Sandoz

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

Tell any doctors, dentists and pharmacists who are treating you

that you are taking Tamoxifen Sandoz.

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are taking Tamoxifen Sandoz.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor if you develop a skin rash or hives

Tell your doctor immediately if you become pregnant while taking tamoxifen Sandoz or within nine months of stopping treatment. This might require termination of pregnancy.

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

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

Unusual bleeding or discharge from the vagina are possible side effects of Tamoxifen Sandoz 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.

Visit your doctor regularly so that he/she can check on your progress.

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

Things you must not do

Do not get pregnant while you are taking Tamoxifen Sandoz.

Ask your doctor about reliable methods of contraception while you are taking Tamoxifen Sandoz.

Do not stop taking Tamoxifen Sandoz or lower the dosage, unless you have discussed this with your doctor.

Do not use this medicine to treat any other complaint unless your doctor says so.

Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Tamoxifen Sandoz affects you.

It may cause dizziness, fatigue or light-headedness in some people.

Side effects

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

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

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- nausea and vomiting
- hot flushes
- distorted sense of taste
- itching around the genital area
- diarrhoea or constipation
- headache, dizziness and light-headedness

- fluid retention
- hair thinning or hair loss
- leg cramps
- fatigue
- 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 bloody supply in the blood vessels of the brain is reduced. These symptoms could be signs of a stroke.

These are all mild side effects of Tamoxifen Sandoz.

Tell your doctor immediately if you notice any of the following:

- any changes in your period
 - unusual/changes in vaginal discharge
 - abnormal vaginal bleeding (e.g. bleeding between periods, heavier than normal bleeding and bleeding after menopause)
 - unusual pain or pressure around your pelvis, in your bones or anywhere in your body
 - excessive thirst as a result of too high calcium blood levels
 - swelling of hands, ankles and feet
 - pain and reddening around the tumour
 - lumps anywhere in the body
 - unusual tiredness, shortness of breath and dizziness when exercising, looking pale
 - frequent infection, fever, severe chills, sore throat or mouth ulcers
 - unexplained bruising
 - skin rash, itchiness or swellings on the skin and hives (if severe rash or blistering of skin tell your doctor immediately or go to the nearest Accident and Emergency)
 - yellowing of the skin or eyes, dark coloured urine
 - disturbance of vision
- 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 any 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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- an unusual cough
- shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips, mouth or other parts of the body; rash, itching or hives on the skin
- severe pain in the chest which may reach the left arm
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your stomach
- severe pain or swelling in either of your legs

Increased risk of blood clots following blockage of a blood vessel by a blood clot and ovarian cysts (in premenopausal women) have been seen with Tamoxifen Sandoz.

These are serious side effects. You may need urgent medical attention or hospitalisation.

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 Sandoz.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Tamoxifen Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C and keep it away from light and moisture.

Do not store Tamoxifen Sandoz or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find out that the expiry date has passed.

Product description

What it looks like

Tamoxifen Sandoz 20 mg tablets are white and round with a notch on one side. They are available in blister packs of 60 tablets.

Ingredients

Active ingredient:

Tamoxifen Sandoz contains 20 mg tamoxifen (as citrate).

Inactive ingredients:

- lactose
- sodium starch glycollate
- povidone
- microcrystalline cellulose
- magnesium stearate
- titanium dioxide
- hypromellose
- macrogol 4000.

Supplier

Australia

Sandoz Pty Ltd

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54 Waterloo Road

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Australia

Tel: 1800 726 369

Australian Register Number

Tamoxifen Sandoz 20 mg tablets:
AUST R 80076 (*blisters*)

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