

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 available information. 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 it is expected to 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.

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 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 take this medicine if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description
- it is past its expiry date or the packaging appears to have been tampered with

- you are pregnant or intend to become pregnant; also if you plan to get pregnant within two months after treatment
- you are breastfeeding or intend to breastfeed. It is unknown if tamoxifen passes into breast milk.

Discuss contraception with your doctor. Although Tamoxifen Sandoz blocks female hormones, it is not a contraceptive. **You should see your doctor immediately if you think you may have become pregnant after starting to take Tamoxifen Sandoz.**

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

Before you start to take Tamoxifen Sandoz

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as tamoxifen citrate
- any other substances, including foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- 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 vaginal bleeding or discharge.

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

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:

- 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).

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.

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 20mg once daily (one Tamoxifen Sandoz 20mg tablet). Doses may be increased to 40mg daily.

How to take it

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

When to take Tamoxifen Sandoz

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 Tamoxifen Sandoz

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, 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

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26 or New Zealand 0800 POISON or 0800 764766) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Tamoxifen Sandoz.

Do this even if there are no signs of discomfort or poisoning.

While you are using Tamoxifen Sandoz

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while taking this medicine.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Tamoxifen Sandoz.

Things you must not do

- Do not stop taking Tamoxifen Sandoz without your doctor's permission.
- 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 or light-headedness in some people.

Side effects

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. **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
- unusual vaginal discharge
- any change in your periods
- itching around the vagina
- diarrhoea or constipation
- headache, dizziness and light-headedness
- hair thinning or hair loss
- leg cramps.

These are all mild side effects of Tamoxifen Sandoz.

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 Sandoz.

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

- 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
- change or disturbance of vision
- pain and reddening around the tumour
- unusual tiredness, shortness of breath and dizziness when exercising, looking pale
- frequent infection, fever, severe chills, sore throat or mouth ulcers
- unexplained bruising
- yellowing of the skin or eyes, dark coloured urine.

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.

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- rash, itching or hives.

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.

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.

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

Return any unused or out of date medicine to your pharmacist.

Product description

What Tamoxifen Sandoz looks like

Tamoxifen Sandoz 20mg 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 20mg tamoxifen (as citrate).

Inactive ingredients:

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

Supplier

Sandoz Pty Ltd
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