

TAMOXIFEN SANDOZ®

tamoxifen citrate tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions people ask 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 will have 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 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 SANDOZ 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 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 SANDOZ reduces, but does not eliminate, the risk of breast cancer.

TAMOXIFEN SANDOZ blocks the actions of oestrogen. Oestrogen is a natural female sex hormone. In some types of breast cancer, oestrogen can help cancer cells to grow.

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 prescribe this medicine for another use. Ask your doctor if you want more information.

TAMOXIFEN SANDOZ is not 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.

Your baby may take 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 use TAMOXIFEN SANDOZ for reducing the risk of breast cancer occurrence if:

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

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.

Before you start to take it

You must tell your doctor if:

1. 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, 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.

2. you have or have ever had any of these medical conditions:

- 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- oral contraceptive ('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 out with TAMOXIFEN SANDOZ.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you take any TAMOXIFEN SANDOZ.

TAKING TAMOXIFEN SANDOZ

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

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

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 it

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 long to take it

Continue taking TAMOXIFEN SANDOZ for as long as your doctor or pharmacist tells you to.

If you forget to take it

If you miss a dose, 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 double the 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 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 764766) for advice, or go to Accident and Emergency at the nearest hospital immediately 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 IT

Things you must 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.

Things you must 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 while you are taking TAMOXIFEN SANDOZ.

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.

Things to be careful of

Be careful driving or operating machinery until you know how TAMOXIFEN SANDOZ affects you.

Some patients may experience dizziness, fatigue or light headedness.

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 side 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.

Ask your doctor or pharmacist to answer any questions you may have.

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
- 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 infections, fever, severe chills, sore throat or mouth ulcers
- unexplained bruising
- yellowing of the skin or eyes, dark coloured urine
- disturbances 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.

TAMOXIFEN SANDOZ may cause or worsen symptoms of hereditary angioedema.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- 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.

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

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

Serious side effects are rare. Tell your doctor if you notice any of the following and they worry you:

- depression
- hot flushes
- nausea and vomiting
- unusual vaginal discharge
- any change in your periods

- itching around the vagina
- diarrhoea or constipation
- headache, dizziness or 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 level 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.

Some people may get other effects while taking TAMOXIFEN SANDOZ.

AFTER USING IT

Storage

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.

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

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.

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

Heat and dampness can destroy some 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 - white, round tablets with a notch on one side.

Available in blisters of 60 tablets.

Ingredients

Active ingredient:

- TAMOXIFEN SANDOZ 20 mg - 20 mg tamoxifen (as citrate)

Inactive ingredients:

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

Supplier

Sandoz Pty Ltd
100 Pacific Highway
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