

TAMOSIN tablets

tamoxifen (as tamoxifen citrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TAMOSIN. It does not contain all of 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 TAMOSIN 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 TAMOSIN is used for

TAMOSIN contains the active ingredient tamoxifen (as tamoxifen citrate). Tamoxifen is an anti-oestrogen medicine and is used to counteract the actions of the naturally occurring female sex hormone, oestrogen.

TAMOSIN is used in the treatment of breast cancer.

TAMOSIN blocks the actions of oestrogen. In some types of breast cancer, oestrogen can help the cancer cells to grow.

Ask your doctor if you have any questions about why TAMOSIN has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

TAMOSIN is not addictive.

Before you take it

When you must not take it

Do not take TAMOSIN if you have ever had an allergic reaction to:

- Tamoxifen
- lactose. This product contains lactose.
- any of the other ingredients listed at the end of this leaflet.

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 TAMOSIN if you are pregnant.

It may affect your developing baby.

Do not take TAMOSIN after the expiry date printed on the pack.

Do not take TAMOSIN if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you are pregnant, may be pregnant or plan to become pregnant.

Taking TAMOSIN during pregnancy can harm your developing baby. Your doctor will discuss the risks involved.

Tell your doctor if you have not been through menopause.

If it is possible that you could become pregnant, you must use a non-hormonal

barrier method of contraception, while you are taking TAMOSIN and for two months after you stop taking it.

Tell your doctor if you are breast feeding or plan to breast feed.

It is not known if tamoxifen is excreted in breast milk so it is not recommended for use while breast feeding.

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

- liver problems
- blood clots in legs, lungs, heart or brain
- any unexplained vaginal bleeding or discharge
- blood disorders such as a low platelet count or a low white blood cell count.

It may not be safe for you to take TAMOSIN if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking TAMOSIN.

Taking other medicines

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

Some medicines and TAMOSIN may interfere with each other. These include coumarin type anticoagulants used to prevent blood clots, such as warfarin, as an increase in the anticoagulant effect may occur. Where co-administration is initiated by your doctor, careful monitoring is required.

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

Avoid taking drugs containing paroxetine, fluoxetine, quinidine, cinacalcet, bupropion, oestrogens, thiazide diuretics and mitomycin.

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

How to take it

How much to take

Your doctor will advise you on what your dose will be.

The usual dose is 20 mg (one tablet) daily. Some people may need to take 40 mg (two tablets) daily. Your doctor will tell you if this is necessary.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

When to take it

Take TAMOSIN at about the same time each day.

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

How long to take it

Keep taking TAMOSIN for as long as your doctor tells you to.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (phone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much TAMOSIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include problems with heart rhythm.

While you are taking it

Things you must do

Tell any other doctors, dentists and pharmacists that are treating you that you are taking TAMOSIN, especially if you are about to be started on any new medicines.

Have regular eye examinations.

Beware of other medicines that are known to increase the risk for eye disorders.

If you experience fatigue while taking tamoxifen, exercise caution when driving or operating machinery.

Tell your doctor immediately if you:

- become pregnant while taking TAMOSIN, or within two months of stopping treatment
- notice any unusual vaginal bleeding or discharge
- pelvic pain or pressure
- notice any changes to your eyesight
- notice any symptoms of blood disorders such as unusual bruising or bleeding.

Tell your doctor that you are taking TAMOSIN if you are about to have any blood tests.

It is very important to keep all of your doctor's appointments, so that your progress can be checked.

Things you must not do

Do not get pregnant while you are taking TAMOSIN.

Do not take TAMOSIN to treat any other complaints unless your doctor tells you to.

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

Do not stop taking TAMOSIN or lower the dosage without checking with your doctor.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking TAMOSIN.

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 if you notice any of the following and they worry you:

- hot flushes
- nausea, vomiting or stomach upset
- headache
- skin rash, itching
- dizziness or lightheadedness
- depression
- swelling of the hands, feet or ankles
- itching around the vagina or genitals
- leg cramps
- hair thinning or hair loss
- aching muscles or muscle tenderness not caused with exercise.

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

- problems with your eyesight
- unusual vaginal bleeding or discharge
- changes in your menstrual periods
- unusual bruising or bleeding
- pain in the bones or at the site of your cancer
- yellowing of the skin and/or eyes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- increase in blood calcium levels, therefore you may notice this as nausea, vomiting and excessive thirst.
- symptoms of a blood clot or if you notice a clot, especially in your arms or legs.
- this list is not exhaustive, please refer to your doctor or pharmacist for a more complete list.

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

Tell your doctor if you have any unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure) when you are taking TAMOSIN or anytime afterwards.

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.

Increased risk of blood clots and ovarian cysts (in premenopausal women) have been reported in patients taking TAMOSIN.

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 reported in patients taking TAMOSIN.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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 taking it

Storage

Keep TAMOSIN in a cool, dry place, protected from light, where the temperature stays below 25°C.

Keep the tablets in the bottle until it is time to take them.

Do not store it in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat or 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product Description

What it looks like

TAMOSIN tablets are round white tablets with “20” embossed on one side. Available in a carton containing a plastic bottle containing 60 tablets.

Ingredients

Active ingredient:

Each TAMOSIN tablet contains tamoxifen citrate, equivalent to 20 mg of tamoxifen.

Inactive ingredients:

- starch-maize
- lactose
- povidone
- sodium starch glycollate
- magnesium stearate.

TAMOSIN tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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AUST R 43527.

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