

GenRx Tamoxifen

Contains the active ingredient, tamoxifen (as tamoxifen citrate)

Consumer Medicine Information

For a copy of a large print leaflet ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine

This leaflet answers some common questions about tamoxifen. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is GenRx Tamoxifen. It is used in the treatment of breast cancer.

Although women have been helped by tamoxifen it is not a cure for breast cancer.

Tamoxifen can be used in two ways. It can help treat a cancer which is in, or has spread from, the breast. It can also be used in women who have had a cancer lump removed. Tamoxifen may decrease or prevent the spread of cancer cells to other parts of the body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Tamoxifen acts mainly by blocking the effects of oestrogen, a female sex hormone found naturally in the body. In some types of breast cancer, oestrogen can help cancer cells grow.

There is no evidence that this medicine is addictive.

Use in children

Do not give this medicine to children.

Tamoxifen is not intended for children, and there is not enough information to recommend using this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **you are pregnant or plan to become pregnant**
Tamoxifen may affect your developing baby if you take it during pregnancy. It should not be used during pregnancy. A small number of unwanted complications, such as birth defects, have been reported with babies of women who have taken tamoxifen.
If you are sexually active, your doctor may

suggest you use a reliable, non-hormonal form of contraception while you are taking tamoxifen and for two months after you have stopped treatment with it.

- **it has passed the expiry date (EXP) printed on the pack**
- **the packaging is torn, shows signs of tampering or it does not look quite right**
- **you have had an allergic reaction to tamoxifen, other anti-oestrogen medicines or any of the ingredients listed at the end of this leaflet**
- **you have had an allergic reaction or are intolerant to lactose. This product contains lactose.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash itching or hives on the skin, fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

It is recommended that you do not take tamoxifen if you are breast-feeding. It is not known if tamoxifen passes into breast milk.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

- 1. You have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 2. You are intolerant or allergic to lactose. These tablets contain lactose.**
- 3. You have or have had any medical conditions, especially the following:**
 - unusual or unexplained vaginal bleeding or "spotting"
 - liver problems
 - problems with your blood.
Your doctor may want to take special care if you have any of these conditions.
- 4. You have not gone through menopause.**
Tamoxifen is normally only given to women who have gone through menopause. If you are premenopausal, menstruation will probably be suppressed. You may also develop cystic ovarian swellings while taking tamoxifen.
- 5. You are currently pregnant or breastfeeding or you plan to become pregnant or breast-feed.**
You must not take it if pregnant, and it is not recommended if you are breast feeding.
- 6. You have recently been vaccinated or plan to get a vaccination.**
- 7. You are planning to have surgery.**
Tell the surgeon or anaesthetist also, as tamoxifen may affect other medicines used during surgery.
- 8. You are currently receiving or are planning to receive dental treatment.**
- 9. You are taking or are planning to take any other medicines.**

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with tamoxifen. These include:

- other medicines used to treat cancer (chemotherapy agents)
- medicines used to prevent blood clots, including warfarin
- rifampicin, an antibiotic used to treat tuberculosis (TB)
- aromatase inhibitors, such as anastrozole, letrozole or exemestane.

If you are taking any of these you may need a different dose or you may need to take different medicines.

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

Other medicines not listed above may also interact with tamoxifen.

How to take this medicine

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

Their instructions may be different to the information contained in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Most people will start their treatment by taking a 20 mg dose once daily. Your doctor may increase this dose to 40 mg a day, depending on your condition and how you respond to the medicine. Patients with liver problems may need smaller doses.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets with a full glass of water. Do not chew or crush the tablets.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

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

However, taking it with food may help prevent stomach upsets.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Tamoxifen helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well. Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you miss a dose, and it is more than 12 hours before your next dose is due, take the missed dose as soon as you remember.

If it is less than 12 hours to your next dose, do not take the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much tamoxifen the effects may include those listed in the 'side effects' section, but are usually of a more severe nature.

There have been reports of heart rhythm problems associated with an overdose of this medicine.

While you are taking this medicine

Things you must do

If you become pregnant while taking this medicine or within two months of stopping treatment, tell your doctor immediately.

Tell your doctor immediately if you notice any unusual gynaecological symptoms especially vaginal bleeding or discharge or pelvic pain or pressure, even if it occurs after treatment with tamoxifen has stopped.

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

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 that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed
- you are about to have any blood tests
- you are going to have surgery. Tell the surgeon or anaesthetist also, as tamoxifen may affect other medicines used during surgery.

Go to your doctor regularly for a checkup. Your doctor may do tests (such as blood pressure, blood tests and routine gynaecological examinations) to make sure the medicine is working and to prevent side effects.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Things you must not do

Do not get pregnant while you are taking tamoxifen.

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

Do not:

- give this medicine to anyone else, even if their symptoms seem similar to yours

- take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Tamoxifen may cause dizziness, light-headedness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

During sexual intercourse, use a reliable method of contraception. Discuss this with your doctor.

Side effects of tamoxifen

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking tamoxifen or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Some are associated with tamoxifen and some may arise from the breast cancer itself.

Some people, such as those who have not had menopause, may have a greater risk of getting some of these side effects.

Tell your doctor or pharmacist if you notice any of the following.

Mostly, these are mild side effects.

- vaginal itching
- mild skin problems such as rash, itching, hives, dry skin or acne
- hot flushes
- headaches, dizziness or light-headedness
- changes in your menstruation (periods)
- hair loss or thinning
- indigestion or stomach upsets
- nausea and/or vomiting
- diarrhoea or constipation
- leg cramps
- muscle tenderness or weakness.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- unusual pain or pressure around your pelvis, in your bones or anywhere in your body, and/or unusual vaginal bleeding or discharge. This is because a number of small changes to the lining of the womb (endometrium) may occur, some of which may be serious and could include cancer.
- pain or tenderness in the upper abdomen (pancreatitis), which may be due to increased levels of fats (triglycerides) in the blood.
- lumps anywhere in the body
- tumour pain and/or reddening around the tumour, or bone pain
- excessive thirst
- problems or changes with your eyesight. Cases of optic nerve diseases have been reported with this medicine and in a small number of cases, blindness has occurred.
- swelling in your hands, feet or ankles

- severe nausea and/or vomiting, constipation and stomach pain
- bleeding or bruising more easily than normal
- any signs of infection (such as fever, chills, sore throat, cough or mouth ulcers)
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- sudden onset of weakness or paralysis of the arms or legs; difficulty in speaking and/or walking; difficulty in holding things; or difficulty in thinking. Any of these may occur because the blood supply in the blood vessels in the brain is reduced - these symptoms could be signs of a stroke
- coughing up of blood, sudden shortness of breath
- symptoms of high calcium levels in the blood such as loss of appetite, thirst, nausea, vomiting, constipation and stomach pain, sometimes together with confusion and muscle weakness
- severe blisters, or bleeding in the lips, eyes, nose, mouth or genitals
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- symptoms of liver abnormalities such as yellowing of the skin or eyes, or dark coloured urine

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

Allergic reactions

If you think you are having an allergic reaction to tamoxifen, stop taking this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and Disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light.

Do not store your medicine 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date your pharmacist can dispose of the remaining medicine safely.

Product description

What GenRx Tamoxifen looks like

GenRx Tamoxifen 20 mg tablets

White, round, convex, tablets with "20" embossed on one side.

A carton containing a bottle of 60 tablets.

Ingredients

Each tablet contains 20 mg of tamoxifen as the active ingredient.

It also contains the following inactive ingredients:

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

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

GenRx Tamoxifen 20mg tablets

AUST R 153122

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia

GenRx is a registered trade mark of Apotex Pty Ltd

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