

# GenRX Tamoxifen Tablets

Tamoxifen (as citrate)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about GenRX Tamoxifen tablets. 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 GenRX Tamoxifen tablets 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 GenRX Tamoxifen is used for

GenRX Tamoxifen tablets are used to 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 GenRX Tamoxifen for reducing the risk of breast cancer occurring, your knowledge of treatment risks becomes more important because you don't currently have breast cancer. GenRX Tamoxifen 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. GenRX Tamoxifen 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 GenRX Tamoxifen reduces, but does not eliminate, the risk of breast cancer.

GenRX Tamoxifen contains the active ingredient tamoxifen, which works by blocking the actions of oestrogen. Oestrogen is a natural female sex hormone. In some types of breast cancer, oestrogen can help cancer cells to grow.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Follow all directions given to you by your doctor.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

This medicine is not approved for use in children.

### Before you take GenRX Tamoxifen

*When you must not take it*

**Do not take GenRX Tamoxifen tablets if you have an allergy to:**

- any medicine containing tamoxifen
- any of the 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

**Tell your doctor if you are taking any other anti-oestrogen medicines. Their use is not recommended.**

**Do not take this medicine if you are pregnant or plan to become pregnant.**

GenRX Tamoxifen should not be used during pregnancy. A small number of unwanted complications, such as birth defects, have been reported in the unborn baby of women who have taken this medicine. However, it has not been shown whether these were due to GenRX Tamoxifen. If sexually active, your doctor may suggest you use a nonhormonal form of contraception while you are taking GenRX Tamoxifen and for two months after you have stopped treatment with it.

**Do not use GenRX Tamoxifen for reducing the risk of breast cancer occurrence if:**

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

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

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

*Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have any allergies to tamoxifen, other anti-oestrogen medicines or any of the ingredients listed at the end of this leaflet.**

**Tell your doctor if you have not been through menopause.**

**Tell your doctor if you plan to become pregnant or breastfeed.**

GenRX Tamoxifen is not recommended for use in pregnancy and breastfeeding.

**Tell your doctor if you smoke. It may increase your risk of serious side effects.**

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

- liver problems
- any blood disorder or problems such as thrombocytopenia or leucopenia
- unusual or unexplained vaginal bleeding or discharge

- deep vein thrombosis (DVT - blood clots in veins of your leg) or pulmonary embolus (blood clots in your lungs).

Your doctor may want to take special care 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 GenRX Tamoxifen.**

*Taking other medicines*

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

Some medicines and GenRX Tamoxifen tablets may interfere with each other. These include:

- oral contraceptives ('the pill')
- hormone replacement therapy
- other medicines used to treat cancer, including chemotherapy
- medicines used to prevent blood clots such as warfarin and heparin
- rifampicin, an antibiotic
- antidepressants such as paroxetine or fluoxetine
- aromatase inhibitors (hormone therapy) such as anastrozole, letrozole or exemestane.

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

**If you are taking any other anti-coagulant medicines, you may require further monitoring by your doctor.**

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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

### How to take GenRX Tamoxifen

**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 on the box, ask your doctor or pharmacist for help.**

*How much to take*

Your doctor will decide how much GenRX Tamoxifen you need to take.

The usual starting dose is 20 mg once a day. Your doctor may increase this dose to 40 mg a day, depending on your condition and how you respond to the medicine.

*How to take it*

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

GenRX Tamoxifen can be taken with or without food.

*When to take it*

**Take your medicine at about the same time each day.**

### How long to take it

Keep taking GenRX Tamoxifen for as long as your doctor recommends.

### 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 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 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) 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 GenRX Tamoxifen. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

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### While you are taking GenRX Tamoxifen

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#### Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

GenRX Tamoxifen should be stopped 3 weeks before undergoing surgery to reduce the risk of blood clots or other complications.

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

Tell your doctor immediately if you become pregnant while taking GenRX Tamoxifen, or within two months of stopping treatment.

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

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

Visit your doctor regularly and keep all of your appointments, so that your progress can be checked.

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

### Things you must not do

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

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

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

You must not get pregnant while you are taking GenRX Tamoxifen tablets. Ask your doctor about reliable methods of contraception while you are taking this medication.

### Things to be careful of

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

This medicine may cause dizziness, light-headedness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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### Side effects

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

This medicine 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. Some are associated with treatment with GenRX Tamoxifen and some may arise from the breast cancer itself. You may need medical attention if you get some of the side effects.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. Younger women may have less side effects.

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

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

- hot flushes, night sweats
- nausea, vomiting
- unusual vaginal discharge or dryness and menstrual irregularities or for premenopausal women, periods stopping
- any changes in your period
- itching around the genital area
- diarrhoea, stomach pain or constipation
- headache, dizziness or light headedness
- fluid retention
- numbness or pins and needles sensation in the hands or feet
- changes in taste
- tiredness
- depression
- hair thinning or hair loss
- leg cramps
- aching muscles or muscle tenderness not caused with exercise
- 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

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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 GenRX Tamoxifen.

Tell your doctor as soon as possible 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 or disturbances in your vision
- pain and reddening around the tumour or bone pain
- lumps anywhere in the body
- unusual tiredness, shortness of breath and dizziness when exercising, and looking pale
- frequent infection, fever, severe chills, sore throat or mouth ulcers
- severe abdominal pain, loss of appetite, nausea, vomiting, and fever
- sensitivity to the sun
- unexplained bruising
- yellowing of the skin or eyes, dark coloured urine

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

Cough and shortness of breath due to a condition known as interstitial pneumonitis have also been reported.

If you have any unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure) when you are taking GenRX Tamoxifen 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.

GenRX Tamoxifen 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:

- rash, itching or hives
- swelling of the face, lips, tongue and/or throat
- wheezing with difficulty breathing

Increased risk of blood clots or blockages in the arteries and cardiovascular events with chest pain. Ovarian cysts (in premenopausal women) have also occurred with tamoxifen.

The above list includes very serious side effects. You may need urgent medical

attention or hospitalisation. These side effects are very rare.

**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.

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## After using GenRX Tamoxifen

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### *Storage*

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Keep the tablets away from light.**

**Do not store GenRX Tamoxifen 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*

**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 that is left over.**

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## Product description

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### *What it looks like*

GenRX Tamoxifen tablets are pink round and biconvex.

Each pack contains 30 or 60 tablets.

This medicine contains sugars as lactose monohydrate

### *Ingredients*

GenRX Tamoxifen contains 20 mg of tamoxifen (as citrate) as the active ingredient.

The tablets also contain the following inactive ingredients:

- maize starch
- lactose monohydrate
- povidone (K30)
- magnesium stearate
- brilliant scarlet 4R.

### *Distributor*

GenRX Tamoxifen is distributed in Australia by:

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121  
www.arrotex.com.au

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