

Package leaflet: Information for the patient

Tamoxifen 20 mg Tablets (as tamoxifen citrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tamoxifen is and what it is used for
2. What you need to know before you take Tamoxifen
3. How to take Tamoxifen
4. Possible side effects
5. How to store Tamoxifen
6. Contents of the pack and other information

1. What Tamoxifen is and what it is used for

The name of your medicine is Tamoxifen 20 mg Tablets (referred to as Tamoxifen in this leaflet). Your medicine comes as a tablet containing the active ingredient tamoxifen which is an ANTI-OESTROGEN. It is used in the treatment of breast cancer. Some tumours are dependent on female sex hormones, oestrogens, in order to grow. As an anti-oestrogen, tamoxifen can prevent naturally occurring oestrogens attaching to tumour cells, which are dependent on them to grow.

2. What you need to know before you take Tamoxifen

Do not take Tamoxifen:

- If you are allergic (hypersensitive) to tamoxifen or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or think you might be pregnant (see 'Pregnancy and breast-feeding' in section 2 of this leaflet for further information). If you are a woman of child-bearing age, a pregnancy test should normally be taken to confirm if you are pregnant before starting treatment.
- If you have had blood clots in the past and the doctor did not know what caused them.
- If someone in your family has had blood clots with the cause not known.
- If your doctor has told you that you have an illness which runs in the family that increases the risk of blood clots.

Do not take Tamoxifen if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tamoxifen Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamoxifen if any of the following apply to you.

When you take tamoxifen, co-administration with the following medicines should be avoided because a reduction of the effect of tamoxifen cannot be excluded: *paroxetine, fluoxetine (antidepressants), bupropion (antidepressant or aid to smoking cessation), quinidine (for example used in the treatment of cardiac arrhythmia) and cincalet/cinacalcet (for treatment of disorders of the parathyroid gland).*

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Tamoxifen treatment. Stop using Tamoxifen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4

If you have a history of hereditary angioedema as Tamoxifen may cause or worsen symptoms of hereditary angioedema. If you experience symptoms such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing, contact a doctor immediately.

In delayed breast reconstruction operation (weeks to years after your primary breast operation whereby your own tissue is moved to shape a new breast) the use of tamoxifen may increase the risk of the formation of blood clots in the small vessels of the tissue flap which may lead to complications.

Operations

If you are going to have an operation (including planned surgery), tell your doctor or pharmacist. They may suggest that you stop taking Tamoxifen for a short time.

During treatment

If you have not yet gone through the menopause, this medicine may stop you having your monthly periods.

In all women, however, this medicine can affect the womb and vagina including, in some, an increased risk of changes in the lining of the womb or the womb itself, some of which may be due to the development of cancerous changes.

If you notice any of the following, talk to your doctor as soon as possible:

- a change in your normal periods, including unusual or unexpected vaginal bleeding
- an unusual or unexpected discharge from the vagina
- and, if you have gone through the menopause and your periods have previously stopped, any unusual vaginal bleeding.

Other medicines and Tamoxifen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Tamoxifen can affect the way some medicines work and some medicines can have an effect on Tamoxifen.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- anticoagulant medicines (to thin your blood) e.g. warfarin.
- medicines known as 'aromatase inhibitors' that are used to treat breast cancer. These include anastrozole, letrozole and exemestane.
- rifampicin, an antibiotic used to treat infections such as tuberculosis (TB).
- paroxetine, fluoxetine (antidepressants).
- bupropion (antidepressant or aid to smoking cessation).
- quinidine (for example used in the treatment of cardiac arrhythmia).
- cinacalcet/cinacalcet (for treatment of disorders of the parathyroid gland).

Pregnancy and breast-feeding

Pregnancy

- Do not take Tamoxifen if you are pregnant, as tamoxifen may affect the growth of your unborn baby.
- Do not become pregnant while taking Tamoxifen. Ask your doctor for advice on what contraceptive to use – Tamoxifen affects how well some contraceptives work.
- If you are taking Tamoxifen and think you have become pregnant, tell your doctor straight away.

If you are **of child-bearing age**, a pregnancy test should normally be taken before you start to take this medicine to confirm that you are not pregnant. If you think you may be pregnant or are planning to have a baby, **do not** take tamoxifen and contact your doctor as soon as possible for advice.

When taking tamoxifen, if sexually active, it is important to use a non-hormonal form of contraception and continue for at least 9 months after treatment has ended.

After stopping treatment, you should wait at least 9 months before planning to have a baby.

Breast-feeding

Women taking tamoxifen should not breast-feed, as tamoxifen may pass into breast milk.

Driving and using machines

Tamoxifen is not likely to affect your ability to drive or use tools or machines. However, tiredness (fatigue) has been reported with the use of Tamoxifen and caution should be observed when driving or operating machinery while such symptoms persist.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tamoxifen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- ◆ Swallow the tablets with a glass of water.
- ◆ The tablets can be taken before or after food.

Adults and older people

To treat breast cancer, the recommended dose is 20 to 40 mg taken once a day or in two divided doses.

Use in children and adolescents

Tamoxifen should not be given to children and adolescents, as the safety and efficacy of this medicine has not been established in this age group.

If you take more Tamoxifen than you should

Contact your doctor or casualty department immediately. In some cases, tamoxifen may affect the electrical activity of the heart which may be seen in tests or you may notice changes in the heart beat or rate.

If you forget to take Tamoxifen

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, do not take the missed dose, and take the next dose on time.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose. If you miss several doses, contact your doctor.

If you stop taking Tamoxifen

Your doctor will normally tell you how long you should take tamoxifen for. In some cases, this may be for at least 5 years. If you do, however, want to stop taking this medicine, it is recommended that you talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Tamoxifen and tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

Very common (may affect more than 1 in 10 people):

- unusual or unexpected vaginal bleeding (including changes in periods) or vaginal discharge.
- A feeling of discomfort in the lower tummy (pelvis) such as pain or pressure.

These effects may mean that there have been changes to the lining of your womb (the endometrium). Sometimes these effects are serious and could include cancer. They can happen during or after treatment with Tamoxifen.

Common (may affect up to 1 in 10 people):

- severe allergic reactions such as sudden breathing difficulties, a skin rash similar to nettle rash or, very rarely, swelling of the mouth, face or throat.
- blood clots in small or large blood vessels. If they occur in the larger blood vessels, you may notice symptoms such as swelling of the calf or leg, chest pain, coughing up blood, shortness of breath, sudden weakness, or sudden swelling of the hands, feet or ankles. You are more likely to suffer from these if you use tamoxifen in combination with other anti-cancer (cytotoxic) medicines.
- sudden confusion, weakness, loss of strength particularly on one side of the body, loss of or confused speech – these may be signs of a reduction in the blood flow to the brain.
- eye problems due to retinopathy (when the retina in the eye breaks down), which may be seen in eye tests.

Uncommon (may affect up to 1 in 100 people):

- cancer of the lining of the womb (the endometrium) or the womb itself – signs of this may include unusual or unexpected vaginal bleeding.
- reduction in white blood cells, which may cause more infections, such as sore throat, or mouth ulcers and fever, than usual.
- swelling of the pancreas (pancreatitis) that may result in severe stomach pain radiating to the back, fever and nausea (feeling sick).
- inflammation of the lungs (pneumonitis) may occur, which may cause a dry cough, progressive difficulty in breathing, swelling of the ends of the fingers, bluish discolouration of the skin and fever.

Rare (may affect up to up to 1 in 1,000 people):

- swelling of the optic nerve behind the eye, which can cause increasingly blurred vision or damage to, or loss of, nerve cells in the optic nerve, which can lead to loss of vision. In some cases, blindness has occurred.
- liver disorders such as cholestasis (when the flow of bile is blocked), injury, inflammation, death of liver cells or liver failure. You may notice yellowing of the skin or eyes, pale stools, dark urine or pain in the stomach and abdomen.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome, toxic epidermal necrolysis] – these side effects occur rarely.

Very rare (may affect up to 1 in 10,000 people):

- a condition in which the body's own immune system becomes overactive and attacks normal healthy tissue including that of the skin (cutaneous lupus erythematosus).

Not known (frequency cannot be estimated from the available data):

- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Tamoxifen may cause or worsen symptoms of hereditary angioedema.

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- hot flushes.
- skin rash.
- feeling sick.
- swollen arms or legs (fluid retention in the body).
- feeling tired.

Common (may affect up to 1 in 10 people):

- reduction in red blood cells, which can make the skin pale and cause weakness or breathlessness (anaemia).
- increase in blood fat (triglyceride) levels.
- light-headedness, headache.
- tingling or pins and needle sensations in the hands and feet.
- changes in taste, being sick, diarrhoea, constipation.
- hair loss.
- visual disturbance such as cataracts (when the lens of your eye becomes cloudy and lets through less light).
- changes in liver enzyme levels (which may be seen in blood tests), development of “fatty liver” where fatty deposits are seen in the liver.
- leg cramps, muscle pain.
- genital itching.
- uterine fibroids or polyps (non-cancerous growths of the womb), thickening of the womb lining.
- Increased risk of blood clots (including clots in small vessels).

Uncommon (may affect up to 1 in 100 people):

- blood disorders, which may cause you to bruise more easily or without explanation or prolonged bleeding, for example, if you cut yourself.
- changes to your vision and difficulty seeing.
- scarring of the liver (cirrhosis).
- Changes in the amount of calcium in your blood. The signs may include feeling very sick, being sick a lot or being thirsty. **Tell your doctor if this happens** because he or she may want to have blood tests,

Rare (may affect up to 1 in 1,000 people):

- severe blood problems. This can make you bruise more easily, get serious infections, or feel tired or breathless.
- changes to the cornea (the outer layer of the eye).
- problems with the nerve that connects your retina to your brain
- swelling of the ovaries, which may cause pain or pressure in the pelvis.
- presence of cells from the lining of the womb outside of the womb (endometriosis).
- vaginal polyps (non-cancerous growths of the vagina).
- red, often itchy spots, similar to the rash of measles.
- inflammation of small blood vessels, which may lead to purple discoloration of the skin.
- a worsening or “flare” of the existing cancer tumour.

Very rare (may affect up to 1 in 10,000 people):

- blistering of skin which is exposed to sunlight or detachment of the nail from the nail bed.
- a skin condition characterised by skin blisters in areas exposed to light, this is due to the increased liver production of a special group of cell pigments (called porphyrins).
- radiation recall – skin rash involving redness, swelling, and/or blistering of the skin after receiving radiation therapy.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance.

Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tamoxifen

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Blister packs: Store in the original package in order to protect from light and moisture.

Bottle packs: Keep the container tightly closed in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tamoxifen contains

Each tablet contains either 20 mg of the active ingredient tamoxifen, as tamoxifen citrate. The other ingredients are mannitol (E421), maize starch, croscarmellose sodium and magnesium stearate.

What Tamoxifen looks like and contents of the pack

The tablets are round, white and marked with a 'G' on one side. On the other side, the 20 mg tablets are marked 'TN/20'.

Tamoxifen Tablets are available in blister or bottle packs of 30, 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Viatrix Limited

Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer(s):

Delpharm, Lille SAS, Parc d'activités de Roubaix Est, Rue de Toufflers 22, CS50070, 59452 Lys Lez Lannoy, France

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