

TAMOXIFEN 10 mg and 20 mg TABLETS

Package leaflet: Information for the patient

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 Tablets and they belong to a group of drugs called anti-oestrogens.
- Tamoxifen is used to treat:
 - breast cancer
 - certain forms of infertility
- Tamoxifen can also reduce the risk of developing breast cancer occurring in those women who have an increased likelihood of developing breast cancer (your risk). It is important that your healthcare professional calculates your risk of developing breast cancer and discusses the result with you before commencing treatment. There are a number of specific tools available to calculate breast cancer risk, based on information such as your age, family history, genetics, reproductive factors (e.g. age when periods started and stopped, had children or not, taken or taking hormonal replacement therapy and/or oral contraceptive pill) and history of breast disease. Although the tools can estimate your risk, it doesn't mean you will get breast cancer, being at increased risk means you have a higher chance of developing breast cancer. If you and your healthcare professional are considering using Tamoxifen for this, it is important to understand the benefits as well as the side effects of taking Tamoxifen because you don't currently have breast cancer and Tamoxifen reduces, but does not stop the risk of developing breast cancer.

If you want to know more about how to decide whether Tamoxifen is right for you, there is more information for patients on the National Institute for Health and Care Excellence website. Ask your doctor to talk to you about the information which is available for patients.

How Tamoxifen works

Oestrogen is a natural substance in your body known as a 'sex hormone'. Some breast cancers need oestrogen to grow and Tamoxifen works by blocking the effects of oestrogen.

2 What you need to know before you take Tamoxifen

Do NOT take Tamoxifen:

- if you are allergic to tamoxifen citrate or any of the other ingredients of this medicine (listed in section 6)
- if you are to be treated for infertility and you or your family have a history of blood clots or a known inherited condition leading to an increased risk of clotting
- if you have had blood clots in the past and the doctor did not know what caused them
- if you are taking medicines used to prevent blood clots such as warfarin
- if you are pregnant, think you might be pregnant, or planning to become pregnant
- if you are taking a medicine called 'anastrozole' (used to treat breast cancer, see section 2 Taking other medicines).

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamoxifen:

- if you have or any member of your family has a history of blood clots, symptoms of which include pain or swelling in the calf of one leg and/or sudden breathlessness. If you experience these symptoms while taking Tamoxifen, you should speak to your doctor immediately
- if you are severely overweight, if you are elderly, following surgery or if you are immobile as there is an increased chance of a blood clot forming
- if you are being treated for breast cancer and are also receiving chemotherapy, as your doctor may also prescribe an anticoagulant to prevent blood clots
- if you are taking any of the following drugs paroxetine, fluoxetine (e.g. antidepressants), bupropion (antidepressant or aid to smoking cessation), quinidine (used in the treatment of cardiac arrhythmia) and cinacalcet/cinacalcet (for treatment of disorders of the parathyroid gland. Co-administration should be avoided because a reduction of the effect of Tamoxifen cannot be excluded.
- if you have experienced abnormal vaginal bleeding including menstrual irregularities, vaginal discharge, and pelvic pain or pressure while taking Tamoxifen in the past.

If you experience any of these symptoms when taking Tamoxifen you should speak to your doctor immediately.

- 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.

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 need to have a liver function test whilst you are taking these tablets, make sure you have told the doctor that you are taking Tamoxifen, as it can affect the results of this test.

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

Tamoxifen therapy may be used to reduce the risk of breast cancer and it can be associated with serious side effects such as blood clots in the veins of your leg (deep vein thrombosis), blood clots in your lungs (pulmonary embolus) and uterine cancer, all of which can be fatal. Other less serious side effects such as hot flushes, vaginal discharge, menstrual irregularities and pelvic pain 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 therapy to reduce the risk of breast cancer may not be appropriate for all women at increased risk. All assessments with your healthcare professional of the potential benefits and risks prior to starting therapy are essential. You should understand that Tamoxifen reduces, but does not eliminate the risk of breast cancer.

Children

This medicine is not for use in children.

Operations

If you are to undergo planned surgery, you should tell your doctor or pharmacist as they may wish to consider stopping your treatment for a short period.

Other medicines and Tamoxifen

Please do not take anastrozole (used to treat breast cancer) while you are taking this medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those you have bought without prescription. In particular, you should inform your doctor if you are taking:

- oral contraceptives
- hormone replacement therapy (HRT)
- antidepressants (e.g. paroxetine, fluoxetine)
- Bupropion (antidepressant or aid to smoking cessation)
- Quinidine (for example used in the treatment of cardiac arrhythmia)
- Cincalet/Cinacalcet (for treatment of disorders of the parathyroid gland)
- any anti-coagulants (used to treat and prevent abnormal blood clotting) e.g. warfarin
- any cytotoxic drugs (used to kill cancer cells)
- Rifampicin (used to treat tuberculosis)
- medicines known as 'aromatase inhibitors' that are used to treat breast cancer. These include anastrozole, letrozole and exemestane.

Contraception

Women of childbearing potential should use adequate non-hormonal contraception (e.g. barrier contraception) while being treated with Tamoxifen citrate and for 9 months following completion of treatment. Please discuss this with your doctor.

Men are recommended to use effective contraceptive measures and to not father a child while receiving Tamoxifen citrate and for 6 months following completion of treatment.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not take Tamoxifen if you are pregnant. This is because it may affect your unborn baby.
- As you should not become pregnant when taking Tamoxifen, please see your doctor for advice on what contraceptive precautions you should take, as some may be affected by Tamoxifen.
- You should see your doctor immediately if you think you may have become pregnant after starting to take Tamoxifen.
- You should not become pregnant while taking Tamoxifen and for nine months after you stop taking it. Please see your doctor for contraception advice.

Driving and using machines

Tamoxifen is not known to affect your ability to drive or operate machinery. However, tiredness has been reported with the use of Tamoxifen and Tamoxifen can cause problems with your ability to see. Caution should be observed while driving or operating machinery while you have such symptoms.

Information about ingredient of Tamoxifen

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

3 How to take Tamoxifen

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

Before commencing any treatment, pregnancy must be excluded by having a pregnancy test if there is any chance that you could be pregnant. The tablets should be swallowed preferably with a glass of water.

The recommended dose is:

Adults and the elderly

- **For the treatment of breast cancer**
20 mg a day. Your doctor will assess whether this dose is appropriate for you.
- **For the treatment of infertility, if you have regular periods**

10 mg twice a day or 20 mg once a day on days 2, 3, 4 and 5 of the menstrual cycle (the first day of bleeding is counted as day 1 of the cycle). If the initial course of treatment is unsuccessful it may be repeated, with

higher doses if necessary, up to a maximum of 80 mg daily in single or divided doses.

• For the treatment of infertility, if you do not have regular periods

10 mg twice a day or 20 mg once a day for four days. This initial course of treatment may begin on any day. If you do not menstruate after the initial course of treatment, your doctor may give you a further course with increased dosage starting 45 days later. If you do menstruate after the initial course of treatment, the next course should start on day 2 of that menstrual cycle.

Reducing the risk of breast cancer

The recommended dose for reducing the risk of breast cancer is 20 mg daily for 5 years.

Your healthcare professional will calculate your risk of breast cancer occurring using information about you, your medical history and any family history of breast cancer.

If you take more Tamoxifen than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Tamoxifen

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tamoxifen

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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:

- symptoms of a blood clot. These include swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak.
- symptoms of a stroke. These include sudden onset of the following: weakness of the arms or legs, being unable to move the arms or legs, difficulty speaking, walking, or holding things, or difficulty thinking. These symptoms are caused by a reduced blood supply in the brain.
- difficulty in breathing.
- swelling of the face, lips, tongue or throat difficulty in swallowing or breathing (angioedema). Tamoxifen may cause or worsen symptoms of hereditary angioedema.
- swelling of the hands, feet or ankles.
- nettle rash (also called 'hives' or 'urticaria').
- blistering/bleeding of the lips, eyes, nose and genitals (Stevens-Johnson syndrome).
- 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.

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

You should speak to your doctor or nurse at once if you notice any of the following gynaecological symptoms:

- unusual bleeding from your vagina
- irregular periods, especially if associated with heavier bleeding as this could be a warning sign for a certain type of cancer affecting the lining of your womb (endometrial cancer)
- 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 of the endometrium/uterus. They can happen during or after treatment with Tamoxifen.

Other side effects:

Very common: may affect more than 1 in 10 people

- nausea
- fluid retention
- skin rash
- hot flushes
- tiredness
- depression

Common: may affect up to 1 in 10 people

- anaemia (a blood problem which means you have too few red blood cells)
- changes in vision due to cataracts or changes to the retina of your eye
- increased amounts of fats in your blood (shown by blood tests)
- allergic reactions
- leg cramp
- changes in the womb (including changes to its lining and benign growths)
- headache
- feeling light-headed
- itching of the genitals
- thinning of the hair
- vomiting
- diarrhoea
- constipation
- changes in blood tests of liver function
- formation of fatty liver cells
- muscle pain
- sensory changes (including taste disorder and numbness or tingling in the skin)
- increased risk of blood clots (including clots in small vessels).

Uncommon: may affect up to 1 in 100 people

- blood problems. This can make you bruise more easily, get serious infections, or feel very tired or breathless.

- changes to your vision and difficulty seeing
- swelling of the pancreas. This may cause moderate to severe pain in the stomach.
- 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 you to have blood tests.
- inflammation of the lungs. The symptoms may be like pneumonia (such as feeling short of breath and coughing).
- liver cirrhosis (problems with your liver).

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 very tired or breathless.
- changes to the cornea of your eye
- problems with the nerve that connects your retina to your brain
- swelling of the optic nerve
- on occasions more severe liver diseases have occurred from which some patients have died. These liver diseases include inflammation of the liver, liver cirrhosis, liver cell damage, reduced bile formation, and failure of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes).
- damage to blood vessels causing red or purple dots in the skin
- severe skin disorder. The symptoms include redness, blistering and peeling.
- cells normally only found in the lining of the womb found elsewhere in your body, cysts on the ovaries, and cancer (the signs of this are given above)
- non-cancerous mass in the inner lining of the vagina (called vaginal polyp)
- at the beginning of treatment, a worsening of the symptoms of your breast cancer such as an increase in pain and/or an increase in the size of the affected tissue may occur (known as tumour flare).

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

- inflammation of the skin characterized by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus)
- a skin condition characterised by skin blisters in areas exposed to the 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 (like severe sunburn) of the skin after receiving radiation therapy.

Not known: frequency cannot be estimated from the available data

- gastro-intestinal intolerance
- bone pain.

Do not be concerned by this list of possible side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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, and keep the tablets in the original bottle or carton supplied. Do not transfer them to another container.

Do not use this medicine after the expiry date that is stated on the carton. The expiry date refers to the last day of that month.

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 tablets contain:

- The active ingredient is either 15.2 mg of Tamoxifen citrate which is equivalent to 10 mg of tamoxifen, 30.4 mg of Tamoxifen citrate which is equivalent to 20 mg of tamoxifen or 60.8 mg of Tamoxifen citrate which is equivalent to 40 mg of tamoxifen.
- The other ingredients are mannitol (E421), povidone (E1201), sodium starch glycolate, colloidal silicon dioxide (E551), magnesium stearate (E572), hypromellose (E464), polyethylene glycol and the colour, titanium dioxide (E171).

What Tamoxifen tablets look like and contents of the pack:

- Tamoxifen 10 mg Tablet: Round biconvex white coated tablets 7 mm diameter with one face blank, the reverse face marked '10' and 'T'.
- Tamoxifen 20 mg Tablet: Round biconvex white coated tablets 9.5 mm diameter with one face blank, the reverse face marked '20' above score line and 'T' below.
- The tablets are available in packs of 30 and 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

Manufacturer

Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.
Dupnitsa 2600, BULGARIA

This leaflet was last revised in June 2024

PL 00289/0477-0478

