

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Tamoxifen 10mg and 20mg Tablets (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

Tamoxifen belongs to a group of medicines called anti-oestrogens. Oestrogen is a natural substance in your body and some breast cancers need oestrogen to grow. Tamoxifen works by blocking the effects of oestrogen.

Tamoxifen is used to:

- Treat breast cancer
- Treat infertility in women caused by a failure to produce and release eggs (ovulate) properly
- 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.

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)
- You are pregnant or think you might be pregnant (see "Pregnancy and Breast-feeding" section)
- You are taking anastrozole, used to treat breast cancer (see "Other medicines and Tamoxifen" section)
- You are being treated for infertility
- You or your family have a history of blood clots with the cause unknown or have an inherited (genetic) condition that increases the risk of blood clots

- You are taking medicines used to prevent blood clots such as warfarin (see “Other medicines and Tamoxifen” section)

Warnings and precautions

Talk to your doctor before taking Tamoxifen:

- 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.
- If you are at risk of developing blood clots, particularly in relation to delayed breast reconstruction surgery (weeks to years after the operation)
- If Tamoxifen is to be used to reduce the risk of breast cancer developing, it is important that your doctor 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 and history of breast disease. These tools can estimate your risk and being at increased risk means you have a higher chance of developing breast cancer but it doesn't mean you will get breast cancer. It is important to understand the side effects as well as the benefits of taking Tamoxifen if you don't currently have breast cancer and that Tamoxifen reduces, but does not stop the risk of developing breast cancer

Children and adolescents

- Tamoxifen is **not** recommended for use in children under 18 years of age.

Operations

If you are to undergo planned surgery, you should tell your doctor as they may wish to consider stopping your treatment with Tamoxifen for a short time.

Other medicines and Tamoxifen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Tell your doctor or pharmacist if you are taking:

- Oral contraceptives
- Hormone Replacement Therapy (HRT)

Medicines which **may** interact with or be affected by Tamoxifen:

- Paroxetine, Fluoxetine, used to treat depression (antidepressants)
- Quinidine, used to treat abnormal heart rhythms (antiarrhythmic agent)
- Cinacalcet/Cinacalcet, used to treat disorders of the parathyroid gland (calcimimetic)
- Bupropion, used to treat depression or as an aid to stop smoking
- Medicines used to thin the blood e.g. warfarin (anticoagulants)
- Other medicines used to treat breast cancer, e.g. anastrozole, letrozole, exemestane
- Rifampicin, used to treat bacterial infections (antibiotic)

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 for advice before taking this medicine.

Pregnancy

- Do **not** take Tamoxifen if you are pregnant or think you may be pregnant.
- You should not become pregnant while taking Tamoxifen and for nine months after you stop taking it. Please see your doctor for contraception advice.
- If you are taking Tamoxifen, you should use non-hormonal (barrier) contraception e.g. condom, diaphragm or coil.

- You should see your doctor immediately if you think you may have become pregnant after starting to take Tamoxifen.

Breast-feeding

- Breast-feeding is not recommended if you are taking Tamoxifen, as it is not known if Tamoxifen is passed into breast milk.
- Your doctor will decide whether you are to discontinue breast-feeding or to discontinue your treatment with Tamoxifen, taking into account the importance of Tamoxifen treatment for you.

Driving and using machines

Although unlikely, you may feel tired, weak or lack energy (fatigue) whilst taking this medicine. If any of these symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

Tamoxifen contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

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.

- These tablets are to be taken orally

Treatment of breast cancer

- The recommended daily dose is 20mg.
- There is no additional benefit in taking a higher dose of Tamoxifen when being used to treat breast cancer.
- Pre-menopausal women may have less frequent periods whilst taking Tamoxifen Tablets.

Treatment of infertility

The possibility of pregnancy must be excluded before starting treatment with Tamoxifen. The dose for infertility depends on your periods (menstrual cycle).

Women with regular periods:

- 20mg of Tamoxifen should be taken on the second, third, fourth and fifth day of your menstrual cycle.
- If your initial course of treatment is unsuccessful, further courses of treatment may be given during subsequent periods, increasing the dose to 40mg and then 80mg daily.

Women with irregular periods:

- The initial course of 20mg daily may begin on any day.
- If there are no signs of period bleeding (ovulation), another course of treatment may begin after 45 days with the dosage increased to 40mg and then 80mg daily.
- If period bleeding (menstruation) does occur, the next course of treatment should begin on the second day of your menstrual cycle.

Reducing the risk of breast cancer

- The recommended dose is 20mg daily for 5 years.
- There is no additional benefit in taking a higher dose or longer period of use.

Use in children

Tamoxifen Tablets are **not** recommended for use in children under 18 years of age.

If you take more Tamoxifen than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take Tamoxifen

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Tamoxifen

It is important that you keep taking Tamoxifen for as long as your doctor has told you to.

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 seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Tamoxifen may cause or worsen symptoms of hereditary angioedema
- Symptoms of a blood clot: swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak
- Symptoms of a stroke: sudden onset of the following: weakness or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty speaking, walking, or holding things, or difficulty thinking
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Blistering of the skin (bullous pemphigoid),
- 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

Seek medical advice immediately if you notice any of the following symptoms:

- Unusual bleeding or a discharge from your vagina
- Irregular periods, especially if associated with heavier bleeding
- A feeling of discomfort, pain or pressure in the lower tummy (pelvis)

Other side effects

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

- Tiredness, weakness or lack energy (fatigue)
- Feeling sick (nausea)
- Fluid retention
- Skin rashes
- Hot flushes
- Depression

Common side effects (may affect up to 1 in 10 people)

- Damage to the retina [light-sensitive tissue lining the back of the eye] (retinopathy)
- Tingling or numbness in the hand or feet (paraesthesia)
- Abnormal sense of taste (dysgeusia)
- Increase in risk of blood clots
- Leg cramp
- Muscle pain (myalgia)
- Increased level of fats (triglycerides) in the blood (detected by blood tests)
- Looking pale and feeling tired (anaemia)
- Cloudy patches in the lens of the eye, causing blurred vision (cataracts)
- Changes in the womb (including changes to the lining and benign growths)
- Headache
- Feeling lightheaded
- Itching of the area around the vagina [vulva] (pruritus vulvae)
- Hair loss (alopecia)
- Being sick (vomiting)
- Diarrhoea
- Constipation

- Changes in liver enzyme levels (detected by blood tests)
- Build-up of excess fats in the liver (fatty liver)

Uncommon side effects (may affect up to 1 in 100 people)

- If you suffer from bone cancer (bony metastases) you may develop high levels of calcium in the blood (hypercalcaemia) on starting treatment with Tamoxifen
- Inflammation of the lungs (interstitial pneumonitis)
- Increased risk of womb (uterus) cancer (endometrial cancer)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- A reduction in white blood cells (leucopenia)
- Visual disturbances
- Inflammation of the pancreas (pancreatitis)
- Scarring of the liver as a result of continuous, long-term liver damage (cirrhosis)

Rare side effects (may affect up to 1 in 1000 people)

- Changes to the cornea (the clear, dome-shaped, window covering the front of the eye)
- A reduction in white blood cells (neutropenia)
- Increased risk of cancer of the muscle and supporting tissues of the womb [uterus] (uterine sarcoma)
- Inflammation of the optic nerve causing blurring, blind spots, distorted vision, reduced colour vision and pain when moving the eyes. In a small number of cases blindness may occur (optic neuropathy/optic neuritis)
- Increase in the size of tumours (tumour flare)
- Inflammation of the liver (hepatitis)
- Build-up of bile acids in the bloodstream causing persistent itch (cholestasis)
- Liver failure or damage (hepatocellular injury/hepatic necrosis)
- Inflammation of the blood vessels in the skin causing a rash (cutaneous vasculitis)
- Condition where small pieces of the womb lining are found outside the womb causing symptoms such as painful periods, persistent pain in the pelvic area and infertility (endometriosis)
- Swelling of ovarian cysts (growth on, or inside, the ovary)
- Small, soft growths (polyps) on the vagina
- More prone to infections due to a severe reduction in number of white blood cells (agranulocytosis)

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

- Condition which causes joint pain, skin rashes and fever (Cutaneous Lupus Erythematosus [CLE])
- Sensitivity of the skin to sunlight (Porphyria Cutanea Tarda [PCT])
- Radiation recall - skin rash involving redness, swelling, and/or blistering (like severe sunburn) of the skin after receiving radiation therapy

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 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 use this medicine after the expiry date, which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Protect from heat. Store in the original package in order to protect from light and moisture.
- 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 to protect the environment.

6 Contents of the pack and other information

What Tamoxifen contains:

- Each 10mg tablet contains 15.2mg of tamoxifen citrate equivalent to 10mg of tamoxifen.

- Each 20mg tablet contains 30.4mg of tamoxifen citrate equivalent to 20mg of tamoxifen.

The other ingredients are: lactose, microcrystalline cellulose, carmellose sodium, povidone, magnesium stearate, potable water.

What Tamoxifen look like and the contents of the pack:

- Tamoxifen 10mg are white, convex tablets printed with “T10” on one side with an approximate diameter of 8mm.
- Tamoxifen 20mg are white, convex tablets printed with “T20” on one side with an approximate diameter of 9.5mm.

Tamoxifen is available in:

Tamoxifen tablets are available in packs of 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Tamoxifen Tablets 10mg: PL 11311/0517
- Tamoxifen Tablets 20mg: PL 11311/0059

Marketing Authorisation Holder & Manufacturer:

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
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LU2 8DL
United Kingdom

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