PACKAGE LEAFLET:
INFORMATION FOR THE USER

Tamoxifen 20 mg Tablets

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

1. What Tamoxifen Tablets are and what they are used for

What Tamoxifen is
Tamoxifen belongs to a group of medicines called 'anti-oestrogens'.

What Tamoxifen is used for
- Tamoxifen is used to treat breast cancer
- It is also used to treat infertility in women caused by 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 of 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 Tablets

Do NOT take Tamoxifen Tablets:
- If you are pregnant or think you might be pregnant (see the section on 'Pregnancy' below).
- If you are allergic to tamoxifen or any of the other ingredients of this medicine (listed in section 6).
- If you are taking anastrozole.
- If you are taking any treatment for infertility.
- 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.
- If you are taking medicines used to prevent blood clots such as warfarin

Do not take Tamoxifen Tablets 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.
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.

Studies in premenopausal women who took tamoxifen for reduction of breast cancer risk or for treatment of breast cancer have reported decreases in bone density. If you are a premenopausal woman undergoing treatment with Tamoxifen, ask your doctor for advice about ways to maintain your bone health.

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 pelvis 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.

If you have or have had heart problems or an irregular heartbeat (arrhythmia), you may be at a higher risk of changes in your heart's electrical activity (known as QT prolongation) when using tamoxifen. QT prolongation can be seen on a heart test called an electrocardiogram (ECG) and may increase the risk of serious heart rhythm problems. If you are at an increased risk, your doctor should check your blood for important blood salts and minerals (electrolytes) and check your heart activity with an ECG before and during treatment with tamoxifen.

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 have any heart conditions including heart rhythm problems (arrhythmia), including a condition called Long QT syndrome (QT interval prolongation), the risk of heart rhythm problems may be increased when using Tamoxifen.

Serious skin reactions
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.

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.

Children
This medicine is not for use in children.

Other medicines and Tamoxifen Tablets
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Tamoxifen can affect the way some other medicines work and some medicines can have an effect on Tamoxifen.
In particular, tell your doctor or pharmacist if you are taking any other medicines:
- Oral contraceptives
- Hormone replacement therapy (HRT)
- Antidepressants (e.g. paroxetine, fluoxetine).
- Bupropion (used as an antidepressant or aid to smoking cessation).
- Quinidine (for example used in the treatment of cardiac arrhythmia).
- Cinacalcet (for treatment of disorders of the parathyroid gland).
- Blood thinning medicines such as warfarin. These are known as 'anticoagulants'.
- Rifampicin which is used for tuberculosis (TB).
- Medicines known as 'aromatase inhibitors' that are used to treat breast cancer. These include anastrozole, letrozole and exemestane.
- Medicines that can affect your heart's electrical activity (known as QT prolonging medications). Taking these medicines with Tamoxifen may increase the risk of heart rhythm problems. Some common examples include certain antibiotics (erythromycin, clarithromycin) and some antidepressants and antipsychotics.
- Medicines known to affect heart rhythm.

Contraception
Women who can become pregnant should use adequate non-hormonal contraception (e.g., barrier contraception) during treatment with Tamoxifen and for an additional nine months after stopping 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.

Pregnancy
- Do not take Tamoxifen tablets if you are pregnant. This is because it may affect your unborn baby.
- Avoid becoming pregnant and breast feeding whilst taking Tamoxifen and for nine months after stopping treatment.
- As you should not become pregnant while taking Tamoxifen tablets, 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 tablets.

Breast-feeding
Talk to your doctor before taking Tamoxifen tablets if you are breast-feeding.

Driving and using machines
Tamoxifen Tablets are not likely to affect your ability to drive or use any tools or machines. However, tiredness has been reported with the use of Tamoxifen Tablets and caution should be observed when driving or operating machinery while such symptoms persist.

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

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3. How to take Tamoxifen Tablets

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

For **oral use** only. Swallow the tablets with a glass of water.

Breast cancer treatment
The recommended dose for breast cancer is 20 mg tablet daily.

Infertility
The dose for infertility depends on your periods (menstrual cycle).

- If you are having regular periods, the recommended dose is one 20 mg tablet daily on the 2nd, 3rd, 4th and 5th days of your period.
- If this does not work, your doctor may suggest that you take a higher dose of Tamoxifen tablets during your next period. If this happens, the recommended dose is 40 mg or 80 mg daily on the 2nd, 3rd, 4th and 5th days of your period.
- If you are not having regular periods, you can start taking the tablets on any day of the month.

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 Tablets than you should
If you take more Tamoxifen tablets than you should, contact your doctor, pharmacist or nearest hospital casualty department **immediately**. Take this leaflet and any remaining tablets with you, if possible.

If you forget to take Tamoxifen Tablets

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

4. Possible Side Effects

Like all medicines, Tamoxifen Tablets 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 or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty with speaking, walking, or holding things, or difficulty in thinking. These symptoms are caused by a reduced blood supply in the brain.
- Difficulty in breathing.
- Swelling of the face, lips, tongue or throat which may make it difficult to swallow.
- Swelling of the hands, feet or ankles.
- Nettle rash (also called 'hives' or 'urticaria').
- 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.
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Nolvadex may cause or worsen symptoms of hereditary angioedema.

Tell your doctor straight away if you notice any of the following:

- 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. They can happen during or after treatment with Tamoxifen tablets.

Other possible side effects:
Very Common (may affect more than 1 in 10 people)

- Nausea
- Fluid retention
- Hot flushes
- Tiredness
- Skin rash
- Depression

Common (may affect up to 1 in 10 people)

- Anaemia (a blood problem which means you have too few red blood cells)
- Increased amounts of fats in your blood (shown by blood tests)
- Allergic reactions.
- Changes in the womb (including changes to its lining and benign growths)
- Feeling light-headed
- Headache
- Itching of genitals
- Vomiting
- Diarrhoea
- Constipation
- Thinning of your hair
- Changes in blood test of liver function
- Formation of fatty liver cells
- Leg cramps
- Muscle pain
- Increased risk of blood clots (including clot in small vessels)
- Changes in vision due to cataracts or changes to retina of your eye.
- Sensory changes (including taste disorder and numbness or tingling in the skin)

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 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.
- Changes to your vision and difficulty seeing.
- Swelling of the pancreas. This may cause moderate to severe pain in the stomach
- 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).
- 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).
- Damage to blood vessels causing red or purple dots in the skin
- Severe skin disorder. The symptoms include redness, blistering and peeling.
- 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).
- Changes in the electrical activity of the heart (ECG QT prolonged).

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):

- Decreased bone mineral density in premenopausal women
- Changes in the electrical activity of the heart (Electrocardiogram QT Prolonged)

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine

5. How to store Tamoxifen Tablets

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. The expiry date refers to the last day of that month.

Store below 25°C. Keep in the original package, away 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 protect the environment.

6. Contents of the pack and other information

What Tamoxifen Tablets contain
The active substance is tamoxifen (as citrate), 20mg per tablet.
The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycollate (Type A), povidone K25, magnesium stearate and colloidal anhydrous silica.

What Tamoxifen Tablets look like and contents of the pack
The tablets are white to off-white colored, round, biconvex, with scoring and '20' embossed on one side. They are available in blister packs of 30 tablets.

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