Package leaflet: Information for the user
Tamoxifen 10mg, 20mg and 40mg Film-Coated Tablets
Tamoxifen citrate

Read all of this leaflet carefully before you start using 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.

The name of your medicine is Tamoxifen 10mg, 20mg or 40mg Film-Coated Tablets. In the rest of this leaflet it is called Tamoxifen Tablets.

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

Tamoxifen Tablets contain a medicine called tamoxifen. This belongs to a group of medicines called 'anti-oestrogens'.

What Tamoxifen Tablets are used for
- Tamoxifen Tablets are used to treat breast cancer
- Tamoxifen Tablets also to treat infertility in women caused by a failure to produce and release eggs (ovulate) properly
- Tamoxifen Tablets 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 Tablets for this, it is important to understand the benefits as well as the side effects of taking Tamoxifen Tablets 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 Tablets work
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 allergic 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 the section on 'Pregnancy' below)
- 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 Tablets.

If you have a history of hereditary angioedema as Tamoxifen Tablets 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 the primary breast operation when your own tissue is moved to shape a new breast) Tamoxifen Tablets 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 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.

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 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 Tablets.

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 Tablets, ask your doctor for advice about ways to maintain your bone health.

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 includes medicines you buy without a prescription and herbal medicines. This is because Tamoxifen Tablets can affect the way some other medicines work and some medicines can have an effect on Tamoxifen Tablets.

In particular, you should tell your doctor or pharmacist if you are taking any of the following medicines:
- Oral contraceptives
- Hormone replacement therapy (HRT)
- Antidepressants (e.g. paroxetine, fluoxetine)
- Bupropion (used as 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)
- Blood thinning medicines such as warfarin. These are known as 'anti-coagulants'
- 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 Tablets may increase the risk of heart rhythm problems. Some common examples include certain antibiotics (erythromycin, clarithromycin) and some antidepressants and antipsychotics).

Contraception
Women who can become pregnant should use adequate non-hormonal contraception (e.g., barrier contraception) during treatment with tamoxifen and for an additional two 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
- 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 Tablets
- 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.

Tamoxifen Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains lactose.

3. How to take Tamoxifen Tablets

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

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

Infertility
The dose for infertility depends on your periods (menstrual cycle).
- If you are having regular periods, the recommended dose is one 20mg 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 40mg or 80mg 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, talk to a doctor or pharmacist straight away.

If you forget to take Tamoxifen Tablets
If you forget to take a dose, take another 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.

Stopping treatment with Tamoxifen Tablets
You should continue to take Tamoxifen Tablets for as long as your doctor tells you to. Do not stop taking the medicine without talking 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 Tablets 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, difficulty in 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). Tamoxifen Tablets 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
- Skin rash
- Hot flushes
- Tiredness.

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)
- 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.

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 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 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 and foil. The expiry date refers to the last day of that month.
Do not use this medicine if you notice visible signs of deterioration such as discoloration.
Do not store above 25°C.
Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container.
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 Citrate.
Tamoxifen 10mg Film-Coated Tablets contain 15.2mg of tamoxifen citrate equivalent to 10mg tamoxifen.
Tamoxifen 20mg Film-Coated Tablets contain 30.4mg of tamoxifen citrate equivalent to 20mg tamoxifen.
Tamoxifen 40mg Film-Coated Tablets contain 60.8mg of tamoxifen citrate equivalent to 40mg tamoxifen.

The other ingredients are lactose, maize starch, pregelatinised maize starch, magnesium stearate, methylhydroxypropylcellulose, propylene glycol and Opaspray white (E171 and E464).

What Tamoxifen Tablets look like and contents of the pack
Tamoxifen 10mg Film-Coated Tablets are white, circular, film-coated tablets marked TAM10 on one face and CP on the reverse.
Tamoxifen 20mg Film-Coated Tablets are white, circular, film-coated tablets marked TAM20 on one face and CP on the reverse.
Tamoxifen 40mg Film-Coated Tablets are white, circular, film-coated tablets marked TAM40 on one face and CP on the reverse.
Tamoxifen Tablets are available in blister strip packs of 28, 30, 56, 60, 84 or 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Tamoxifen 10mg Film-Coated Tablets	29831/0194
Tamoxifen 20mg Film-Coated Tablets	29831/0195
Tamoxifen 40mg Film-Coated Tablets	29831/0196

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