Warnings and precautions

- Increases the risk of blood clots.

- If someone in your family has had blood clots with the cause not known.

- If you have had blood clots in the past and the doctor did not know what caused them.

- If you are taking any treatment for infertility.

- If you are taking anastrozole.

- If you are allergic to tamoxifen or any of the other ingredients of this medicine (listed below).

- If you are pregnant or think you might be pregnant (see the section on ‘Pregnancy’).

Talk to your doctor or pharmacist before taking Tamoxifen.

Do NOT take Tamoxifen Tablets:

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

Tamoxifen belongs to a group of medicines called anti-estrogens. Oestrogen is a natural substance in your body known as a ‘sex hormone’. Tamoxifen works by blocking the effects of oestradiol.

- 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.

2. What you need to know before you take Tamoxifen Tablets

- If you are not having regular periods, you can start taking the tablets on any day of your period.

- If you are having regular periods, the recommended dose is one 20 mg tablet daily.

- 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.

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.

- In particular, you should tell your doctor or pharmacist if you are taking any of the following medicines:
  - Antidepressants (e.g. paroxetine, fluoxetine).
  - Bupropion (used as 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 medicine such as warfarin. These are known as ‘anticoagulants’.
  - Rifampicin (an antibiotic used in the treatment of tuberculosis).
  - Medicines known as ‘aromatase inhibitors’ that are used to treat breast cancer, such as anastrozole.

4. Possible side effects

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

Breastfeeding

- Do not take Tamoxifen tablets if you are breastfeeding.

5. How to store Tamoxifen Tablets

- This medicine is not for use in children.

6. Contents of the pack and other information

- This leaflet contains important information for you.
- It includes any possible side effects not listed in this leaflet. See section 4.

Packaging and label

- It contains one bottle of 20 tablets.

Product number

- 0160168

3. How to take Tamoxifen Tablets

- 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.

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 can affect the way some other medicines work and some medicines can have an effect on Tamoxifen.

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

- Antidepressants (e.g. paroxetine, fluoxetine).
- Bupropion (used as 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 medicine such as warfarin. These are known as ‘anticoagulants’.
- Rifampicin (an antibiotic used in the treatment of tuberculosis).
- Medicines known as ‘aromatase inhibitors’ that are used to treat breast cancer, such as anastrozole.

Pregnancy and breast-feeding

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

Breastfeeding

- Do not take Tamoxifen tablets if you are breastfeeding.

Driving and using machines

- Tamoxifen Tablets are not expected to affect your ability to drive or operate machinery. However, you should not perform any tasks requiring special attention until you know how the medicine affects you.

6. Contents of the pack and other information

- This leaflet contains important information for you.
- It includes any possible side effects not listed in this leaflet. See section 4.

Packaging and label

- It contains one bottle of 20 tablets.

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Changes to your vision and difficulty seeing. She may want you to have blood tests.

Changes in the amount of calcium in your blood. The signs may include feeling very tired or breathless.

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

Problems with the nerve that connects your retina to your brain.

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 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).

Cysts on the ovaries, and cancer (the signs of this are given above).

Water retention.

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).

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

Changes to the corneas of your eye.

Swelling of the optic nerve.

Skin problems. This can make you have rash, bruises with red or purple dots on skin and prolonged bleeding from wounds (Thrombocytopenia).

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

• Unusual bleeding from your vagina.
• Irregular periods.
• Vaginal discharge.
• A feeling of discomfort in the lower tummy (pelvis) such as pain or pressure. This is because a number of changes to the lining of the womb may occur, some of which may be 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

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
• Thriving 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.

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 corneas 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).

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.

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. By reporting side effects you can help provide more information on the safety of this medicine.

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 glycolate (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.

Marketing Authorisation Holder and Manufacturer

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