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 take it for anyone else.
- 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 stop taking Tamoxifen Tablets
6. Contents of the pack and other information

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

Tamoxifen is Tamoxifen belongs to a group of medicines called 'selective oestrogen receptor modulators' (SERMs). 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) or by failure to produce and release eggs (ovulate) or by failure to produce and release eggs (ovulate). Tamoxifen can also reduce the risk of developing breast cancer occurring in those women who have an increased likelihood of developing breast cancer due to a family history. 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 taken any treatment for infertility (and/or oral contraceptive pill) and history of breast disease. Although these tools can estimate your risk, they don'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 order this information which is available for patients.

2. How to take Tamoxifen Tablets

2.1. How 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 an anticoagulant.
- If you are taking any treatment for infertility.
- If you have had blood clots in the past and the cause is not known.
- If you have had blood clots in the past and the cause is not known.
- If your doctor has told you that you have an increased risk of getting a blood clot in the family that increases the risk of blood clots.
- If you are taking medicines used to prevent blood clots but the cause is not known.
- If you are taking medicines used to prevent blood clots but the cause is not known.
- New data about this medicine makes it necessary that you start taking the tablets on any day of the menstrual cycle.

Do not take Tamoxifen Tablets if any of the above applies 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.

- Tamoxifen may increase the risk of the formation of blood clots in the small veins of the tissue flap which may lead to complications. Tamoxifen therapy may be reduced to use the risk of blood clots. This may be associated with serious side effects such as blood clots in the veins of your legs (deep vein thrombosis), blood clots in your lungs (pulmonary embolism) and ulcerine cancer, all of which are serious if left untreated. Other less serious side effects such as hot flushes, vaginal discharge, menopausal irregularities and pelvis pain may also occur.

3. How to take Tamoxifen Tablets

The recommended dose is 20 mg daily on the 2nd, 3rd, 4th and 5th days of each month. If this does not work, your doctor may suggest that you take a higher dose of Tamoxifen Tablets during your next period. The maximum 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.

4. Possible side effects

Some serious 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 these symptoms related to these serious skin reactions described in section 4.

Operations

If you are under go emergency surgery, you should see your doctor or pharmacist for advice before taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may have become pregnant after you have taken the tablets, please see your doctor or pharmacist for advice on what contraceptive precautions you should take, as some may be affected by Tamoxifen.

Contraception

Women who can become pregnant should use contraception (see the section on 'Pregnancy' below) during treatment with Tamoxifen and for nine months after stopping treatment.

Breast-feeding

If you are breast-feeding, think you may have become pregnant after you have taken the tablets, please see your doctor or pharmacist for advice before taking this medicine.

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 affect on Tamoxifen. In particular, you should tell your doctor or pharmacist if you are taking any other medicines:

- Oral contraceptives
- Hormone replacement therapy
- Antidepressants (e.g. paroxetine, fluoxetine).
- Bupropion (used as antidepressant or aid to smoking cessation)
- Quinidine (for example used in the treatment of heart rhythm disorders)
- Cisatracurium (for treatment of disorders of the bowel)
- Blood thinning medicine such as warfarin.
- These are known as 'anticoagulants'.
- Rifampicin which is used for tuberculosis (TB).
- Medicines which are known as 'antifungal' or are used to treat breast cancer. These include anidulafungin, fluconazole and itraconazole.

Stop using 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 the last dose of the medicine.

As you should not become pregnant while taking Tamoxifen Tablets, you should discuss this with your doctor for advice on what contraceptive precautions you should take, as some may be affected by Tamoxifen.

You should see your doctor before starting treatment if you think you may have become pregnant after starting to take Tamoxifen Tablets.

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 for at least one month after stopping treatment.

Breast-feeding

If you are breast-feeding, think you may have become pregnant after starting to take Tamoxifen Tablets, please see your doctor or pharmacist for advice before taking the tablets.

Breast-feeding

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

5. How to stop taking Tamoxifen Tablets

Always stop taking Tamoxifen Tablets exactly as your doctor has told you to. 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 daily.

Infertility

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

- If you are having regular periods, the recommended dose is 20 mg for the first 5 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 and let you know if your family history of breast cancer is a factor.

If you take Tamoxifen Tablets you should

• 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, even if this is more than 12 hours after your usual time to take it. 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. Depending on how serious they are, they may not be everybody.

Stop taking Tamoxifen and tell your doctor straight away if you notice any of the following side effects:

Changes in the amount of calcium in your blood. This 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 speech difficulty, weakness or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty with speaking, walking, or hearing things, or difficulty in thinking. These symptoms are caused by a reduced blood supply to the brain.

• Difficulty in breathing.

• Swelling of the face, lips, tongue or throat.

• Swelling of the face, lips, tongue or throat which is associated with breathing difficulty.

• Nettle rash (also called ‘hives’ or ‘urticaria’).

• Nettle rash associated with targeted or circular patches on the skin. Often with central blisters, skin peeling, urns 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.

• Headache

• Feeling light-headed

• Allergic reactions.

• Anemia (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 weight (including changes to its lining and benign growths)

• Arthritis

• Headache

• Changes in the lining of genitals

• Vomiting

• Diarrhoea

• Numbness

• Thinning of your hair

• Changes in blood level of liver function

• Formation of fatty liver cells

• Leg cramps

• Muscle pain

• Changes in the amount due to castrate or changes to retina of your eye.

• Sensitivity (including taste disorder and numbness or tingling in the skin).

Uncommon (may affect up to 1 in 100 people)

• Blood tests with 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.

• Inflammation of the lungs. The symptoms may be like pneumonia (such as feeling short of breath and coughing).

• Non-cancerous (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, jaundice (yellowing of the eyes and skin).

• Cellulitis usually only found in the lining of the wound found elsewhere in your body, casts on the ovaries, and cancer (the signs of this are given above).

• Non-cancerous mass in the inner lining of the womb.

• Damage to blood vessels causing red or purple spots on 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).

Very Rare (may affect up to 1 in 10,000 people)

• Skin inflammation caused by rash or erythema, very often on areas exposed to light—this condition called cutaneous lupus erythematosus.

• A skin condition characterised by skin blisters in areas exposed to the light, this is due to the reduced production of a group of cells called porphyrins.

• Severe difficulty in swallowing, swelling, and/or blistering (like severe sunburn) of the skin.

• Swelling of the face, lips, tongue or throat which is associated with breathing difficulty.

• Difficulty in breathing.

• Changes in the amount of calcium in your blood. This 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 speech difficulty, weakness or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty with speaking, walking, or hearing things, or difficulty in thinking. These symptoms are caused by a reduced blood supply to the brain.

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• Sensitivity (including taste disorder and numbness or tingling in the skin).

5. Possible 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: mhra.gov.uk/yellowcard or search for MHRRA Yellow Card in the Google Play store.

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

6. 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.

7. Contents of the pack and other information

What Tamoxifen Tablets contain

The active substance is tamoxifen citrate, 20mg per tablet.

The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycolate (Type A), povidone K32, magnesium stearate and colloidal anhydrous silica.

What Tamoxifen Tablets look like and contents of the pack

The tablets are white to off-white coloured, round, biconvex, with scoring and 20’ embossed on one side. They are available in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Mithmipharm Limited
Aries, Odyssey Business Park, West End Road South Ruislip, HA4 6QD, United Kingdom

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South Ruislip, HA4 6QD, United Kingdom

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