

TAMOXIFEN 10 mg, 20 mg AND 40 mg TABLETS

Package leaflet: Information for the patient

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
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1 What Tamoxifen is and what it is used for

- The name of your medicine is Tamoxifen Tablets and they belong to a group of drugs called anti-oestrogens.
- Tamoxifen is used to treat:
 - breast cancer
 - certain forms of infertility.

2 What you need to know before you take Tamoxifen

Do NOT take Tamoxifen:

- if you are allergic to tamoxifen citrate or any of the other ingredients of this medicine (listed in section 6)
- if you are to be treated for infertility and you or your family have a history of blood clots or a known inherited condition leading to an increased risk of clotting
- if you are pregnant or planning to become pregnant
- if you are taking a medicine called 'anastrozole' (used to treat breast cancer, see section 2 Taking other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamoxifen:

- if you have or any member of your family has a history of blood clots, symptoms of which include pain or swelling in the calf of one leg and/or sudden breathlessness. If you experience these symptoms while taking Tamoxifen, you should speak to your doctor immediately
- if you are severely overweight, if you are elderly, following surgery or if you are immobile as there is an increased chance of a blood clot forming
- if you are being treated for breast cancer and are also receiving chemotherapy, as your doctor may also prescribe an anticoagulant to prevent blood clots
- if you are taking any of the following drugs: paroxetine, fluoxetine (e.g. antidepressants), bupropion (antidepressant or aid to smoking cessation), quinidine (used in the treatment of cardiac arrhythmia) and cinacalcet/cinacalcet (for treatment of disorders of the parathyroid gland). Co-administration should be avoided because a reduction of the effect of Tamoxifen cannot be excluded.
- if you have experienced abnormal vaginal bleeding including menstrual irregularities, vaginal discharge, and pelvic pain or pressure while taking Tamoxifen in the past.

If you experience any of these symptoms when taking Tamoxifen you should speak to your doctor immediately.

If you need to have a liver function test whilst you are taking these tablets, make sure you have told the doctor that you are taking Tamoxifen, as it can affect the results of this test.

Other medicines and Tamoxifen

Please do not take anastrozole (used to treat breast cancer) while you are taking this medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those you have bought without prescription. In particular, you should inform your doctor if you are taking:

- Paroxetine, fluoxetine (e.g. antidepressants)
- Bupropion (antidepressants or aid to smoking cessation)
- Quinidine (for example used in the treatment of cardiac arrhythmia)
- Cinacalcet (for treatment of disorders of the parathyroid gland)
- any anti-coagulants (used to treat and prevent abnormal blood clotting) e.g. warfarin
- any cytotoxic drugs (used to kill cancer cells)
- Rifampicin (used to treat tuberculosis).

Pregnancy and breast-feeding

You should not take Tamoxifen if you are pregnant or 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. You should use an effective method of non-hormonal contraception such as the barrier method (e.g. the diaphragm or condoms) whilst being treated with Tamoxifen and for 2 months after treatment has stopped.

Driving and using machines

Tamoxifen is not known to affect your ability to drive or operate machinery.

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.

Before commencing any treatment, pregnancy must be excluded by having a pregnancy test if there is any chance that you could be pregnant. The tablets should be swallowed preferably with a glass of water.

The recommended dose is:

Adults and the elderly

- **For the treatment of breast cancer**
20 mg a day. Your doctor will assess whether this dose is appropriate for you.
- **For the treatment of infertility, if you have regular periods**

10 mg twice a day or 20 mg once a day on days 2, 3, 4 and 5 of the menstrual cycle (the first day of bleeding is counted as day 1 of the cycle). If the initial course of treatment is unsuccessful it may be repeated, with higher doses if necessary, up to a maximum of 80 mg daily in single or divided doses.

- **If you do not have regular periods**

10 mg twice a day or 20 mg once a day for four days. This initial course of treatment may begin on any day.

If you do not menstruate after the initial course of treatment, your doctor may give you a further course with increased dosage starting 45 days later. If you do menstruate after the initial course of treatment, the next course should start on day 2 of that menstrual cycle.

If you take more Tamoxifen than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Tamoxifen

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tamoxifen

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)

- blistering/bleeding of the lips, eyes, nose and genitals (Stevens-Johnson syndrome).

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

You should speak to your doctor if you notice any of the following side effects as these are all symptoms of a blood clot. You may need urgent medical treatment:

- The symptoms of a blood clot include pain and swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak.

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 stroke. These include sudden onset of the following: weakness of the arms or legs, being unable to move the arms or legs, difficulty speaking, walking, or holding things, or difficulty thinking. These symptoms are caused by a reduced blood supply in the brain.

You should speak to your doctor or nurse at once if you notice any of the following gynaecological symptoms:

- Abnormal vaginal bleeding including menstrual irregularities
- 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 of the endometrium/uterus. They can happen during or after treatment with Tamoxifen.

Other side effects:

Very common: may affect more than 1 in 10 people

- Nausea.
- Fluid retention.
- Skin rash.
- Hot flushes.

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).
- 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.

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).

Very rare: may affect up to 1 in 10,000 people

- 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).

Not known: frequency cannot be estimated from the available data

- Gastro-intestinal intolerance
- Bone pain
- Inflammation of the skin characterized by rash or erythema, very often on areas exposed to light (a condition called cutaneous lupus erythematosus).
- Recall phenomenon (an acute inflammatory reaction confined to areas previously treated with radiotherapy).

Do not be concerned by this list of possible side effects. You may not get any of them.

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

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 store above 25°C, and keep the tablets in the original bottle or carton supplied. Do not transfer them to another container.

Do not use this medicine after the expiry date that is stated on the carton. The expiry date refers to the last day of that month.

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 tablets contain:

- The active ingredient is either 15.2 mg of Tamoxifen citrate which is equivalent to 10 mg of tamoxifen, 30.4 mg of Tamoxifen citrate which is equivalent to 20 mg of tamoxifen or 60.8 mg of Tamoxifen citrate which is equivalent to 40 mg of tamoxifen.
- The other ingredients are mannitol (E421), povidone (E1201), sodium starch glycolate, colloidal silicon dioxide (E551), magnesium stearate (E572), hypromellose (E464), polyethylene glycol and the colour, titanium dioxide (E171).

What Tamoxifen tablets look like and contents of the pack:

- Tamoxifen 10 mg Tablet: Round biconvex white coated tablets 7 mm diameter with one face blank, the reverse face marked '10' above score line and 'T' below.
- Tamoxifen 20 mg Tablet: Round biconvex white coated tablets 9.5 mm diameter with one face blank, the reverse face marked '20' above score line and 'T' below.
- Round biconvex white coated tablets 11.1 mm diameter with one face blank, the reverse face marked '40' above the score line and 'T' below.
- The tablets are available in packs of 30 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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