

PACKAGE LEAFLET

Package leaflet: Information for the patient

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 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
5. How to store Tamoxifen
6. Contents of the pack and other information

1. What Tamoxifen is and what it is used for

Tamoxifen belongs to a group of medicines called anti-oestrogens. Anti-oestrogens block the effects of a hormone called oestrogen in your body. Tamoxifen is used:

- in the treatment of breast cancer
- to stimulate ovulation (the production of an egg) in women who suffer from a condition called anovulatory infertility. This is when you may have regular, or irregular, menstruation (periods) but you do not ovulate (release an egg)
- 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 pills) and a 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 for 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

Do not take Tamoxifen:

- 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 'Pregnancy and breast-feeding' in

section 2 of this leaflet for further information). If you are a woman of child-bearing age, a pregnancy test should normally be taken to confirm if you are pregnant before starting treatment.

- If you are taking another medicine for the treatment of breast cancer known as anastrozole
- If you are taking any treatment for treating your infertility
- If you have had blood clots in the past and the doctor did not know what caused them
- If you have a family history of 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 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tamoxifen.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tamoxifen.

When you take tamoxifen, you have a 2 to 3 times increased risk of developing a blood clot in your vein. You should speak to your doctor before taking this medicine as the risk is greater if:

- you are elderly
- you or a member of your family have had a blood clot in the past
- you are very overweight (obese), smoke (or have smoked in the past) or have heart or circulatory problems
- you are being given chemotherapy for your 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 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 your doctor considers that you are at risk of blood clots, they may give you an anticoagulant. This is a medicine that thins your blood and reduces your risk of forming a blood clot.

When you take tamoxifen to treat breast cancer, you may stop having your monthly periods.

Surgery and immobility

If you are to have surgery, or you will be unable to move around for a long time, you should take the following precautions:

- If you are taking tamoxifen for infertility: you should stop taking tamoxifen at least 6 weeks beforehand and you should not start taking tamoxifen again until you are fully mobile.
- If you are taking tamoxifen for breast cancer: your doctor may decide that it is better to carry on taking tamoxifen. You may be given special stockings called compression stockings to wear whilst you are in hospital or they may give you an anticoagulant. These reduce the risk of a blood clot.

Tamoxifen treatment 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 pelvic 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.

Children

This medicine is not for use in children.

Other medicines and Tamoxifen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take tamoxifen if you are taking another medicine for the treatment of breast cancer such as anastrozole, letrozole and exemestane.

Also, tell your doctor if you are taking:

- Oral contraceptives
- Hormone replacement therapy (HRT)
- Paroxetine, fluoxetine (e.g. selective serotonin reuptake inhibitor (SSRI) antidepressants)
- Bupropion (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)

or the following:

- anticoagulant medicines (to thin your blood), e.g. warfarin. Tamoxifen may increase the effects of these medicines. Your doctor will monitor your blood regularly, especially when you start or stop treatment
- cytotoxic agents (used to treat cancer). These medicines increase the risk of a blood clot. Your doctor may give you another medicine to stop your blood clotting too easily.
- rifampicin, an antibiotic used to treat infections such as tuberculosis (TB).

Pregnancy and breast-feeding

Do not take Tamoxifen if you are pregnant or breast-feeding as this medicine could harm your baby.

If you are taking tamoxifen for the **treatment of infertility**, you must always take a pregnancy test before you start to take this medicine. If the result is positive, or you are not sure, **do not** take tamoxifen and talk to your doctor.

If you are taking tamoxifen for the **treatment of breast cancer and are of child-bearing age**, a pregnancy test should normally be taken before you start to take this medicine to confirm that you are not pregnant. If you think you may be pregnant or are planning to have a baby, **do not** take tamoxifen and contact your doctor as soon as possible for advice.

When you are taking tamoxifen, if you are sexually active, you should use a barrier method or other non-hormonal method of contraception (e.g. condom). You should not become pregnant while taking this medicine and for nine months after you stop taking it. Please see your doctor for contraception advice.

Do not breast-feed your baby while taking this medicine and for nine months after stopping

treatment. Tamoxifen may pass into breast milk.

Driving and using machines

Do not drive or operate machinery if you feel light-headed, or you have eyesight problems while taking this medicine.

Tamoxifen contains sodium

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

3. How to take Tamoxifen

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

- Swallow the tablets with a glass of water
- You can take Tamoxifen with or without food

The recommended doses in adults are:

Breast cancer:

20 mg per day.

Anovulatory infertility:

If you have regular periods:

You should take Tamoxifen on the second, third, fourth and fifth days of the menstrual cycle. The recommended initial dose is 20 mg daily in either one or two doses.

If this is unsuccessful an increased dose may be given during following menstrual periods: 40 mg then 80 mg daily in either one or two doses.

If you have irregular periods:

You may start treatment with Tamoxifen on any day. If your first course of treatment is unsuccessful, you may be given an increased dose after an interval of 45 days. The higher dose is 40 to 80 mg daily in either one or two doses. If you respond to treatment by menstruating, your next course of treatment should start on the second day of your cycle.

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.

Elderly

You will usually be given the normal adult dose.

Use in children and adolescents

Children and adolescents should not take Tamoxifen.

If you take more Tamoxifen than you should

Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. In some cases, tamoxifen may affect the electrical activity of the heart which may be seen in tests or you may notice changes in the heart beat or rate.

If you forget to take Tamoxifen

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not

take a double dose to make up for a forgotten dose.

If you stop taking Tamoxifen

Do not stop taking Tamoxifen without speaking 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.

If any of the following happen, **stop taking Tamoxifen and tell your doctor immediately** or go to your nearest hospital emergency department:

Very common (may affect more than 1 in 10 people):

- vaginal bleeding

Common (may affect up to 1 in 10 people):

- severe allergic symptoms such as sudden breathing difficulties, dizziness, swelling of the mouth, face or throat, hives, or a skin rash similar to nettle rash.
- blood clots in small or large blood vessels. If they occur in the larger blood vessels, you may notice symptoms such as swelling of the calf or leg, chest pain, coughing up blood, shortness of breath, sudden weakness, or sudden swelling of the hands, feet or ankles. You are more likely to suffer from these if you use tamoxifen in combination with cytotoxic (anti-cancer) agents.
- sudden confusion, weakness, loss of strength particularly on one side of the body, confused or loss of speech – these may be signs of a reduction on the blood flow to the brain.
- eye problems due to retinopathy (when the retina in the eye breaks down)

Uncommon (may affect up to 1 in 100 people):

- cancer of the lining of the womb (the endometrium)
- reduction in white blood cells, which may cause more infections than usual such as fever, severe chills, sore throat or mouth ulcers
- swelling of the pancreas (pancreatitis) that may result in stomach pain radiating to the back, fever and nausea (feeling sick)
- inflammation of the lungs (pneumonitis) may occur, which may cause a dry cough, progressive difficulty in breathing, swelling of the ends of the fingers, bluish discolouration of the skin and fever

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

- the cancer of womb
- swelling of the optic nerve behind the eye, which can cause increasingly blurred vision.
- damage to, or loss of, nerve cells in the optic nerve, which can lead to loss of vision
- liver disorders such as cholestasis (when the flow of bile is blocked), injury, inflammation, death of liver cells or liver failure. You may notice yellowing of the skin or eyes, pale stools, dark urine or pain in the stomach and abdomen
- 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.

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

- condition in which the body's own immune system becomes overactive and attacks normal healthy tissue including that of the skin (cutaneous lupus erythematosus)

Not known (cannot be estimated from the available data):

- swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Tamoxifen may cause or worsen symptoms of hereditary angioedema.

These side effects are serious. You may need medical attention.

The following side effects generally occur after long-term use with Tamoxifen and include a range of menstrual disorders (see below). If you still have periods you may notice that your cycles are disturbed, or may completely stop.

Very common (may affect more than 1 in 10 people):

- vaginal discharge
- hot flushes
- skin rash
- feeling sick
- swollen arms or legs (fluid retention in the body)
- feeling tired
- depression

Common (may affect up to 1 in 10 people):

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- increase in blood fat (triglyceride) levels
- light-headedness, headache
- tingling or pins and needles sensations in the hands and feet
- changes in taste, being sick, diarrhoea, constipation
- hair loss
- tumour pain
- visual disturbance such as cataracts (when the lens of your eye lets through less light)
- changes in liver enzyme levels (which may be seen in blood tests), development of “fatty liver” where fatty deposits are seen in the liver
- leg cramps, muscle pain
- genital itching
- uterine fibroids or polyps (non-cancerous growths of the womb), thickening of the womb lining

Uncommon (may affect up to 1 in 100 people):

- blood disorders which may cause you to bruise or bleed more easily or without explanation
- scarring of the liver (cirrhosis), normally due to liver damage
- high levels of calcium in your blood
- changes to your vision and difficulty seeing.

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

- short-lived falls in platelet counts (platelets are blood cells)
- changes to the cornea (the outer covering of your eye).
- abnormal or interrupted menstrual cycle (periods) in premenopausal women
- swelling of the ovaries, which may cause pain or pressure in the pelvis
- presence of cells from the lining of the womb outside of the womb (endometriosis)
- vaginal polyps (non-cancerous growths of the vagina)
- red, often itchy spots, similar to the rash of measles
- inflammation of small blood vessels which may lead to purple discoloration of the skin
- a worsening or “flare” of the existing cancer tumour

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

- inflammation of a vein due to a blood clot (thrombophlebitis).
- blistering of skin which is exposed to sunlight or detachment of the nail from the nail bed
- radiation recall – skin rash involving redness, swelling, and/or blistering (like severe sunburn) of the skin after receiving radiation therapy.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any 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

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

Do not store above 25°C.

Pots: Keep the pot tightly closed in order to protect from light and moisture.

Blisters: Store in the original package in order to protect 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 used. These measures will help protect the environment.

6. Content of the pack and other information

What Tamoxifen contains

The active substance is tamoxifen citrate. Each 20 mg tablet contains 30.4 mg tamoxifen citrate equivalent to 20 mg tamoxifen.

The other ingredients are mannitol, maize starch, croscarmellose sodium and magnesium stearate.

What Tamoxifen looks like and contents of the pack

Your medicine comes as a white, round, biconvex tablet marked with TN|20 on one side and G on the other.

Tamoxifen is available in blister packs or plastic containers, with an optional plastic spacer at the top of the pack of 5, 7, 10, 14, 20, 21, 25, 28, 30, 50, 56, 60, 100 and 250 tablets. Not all pack sizes may be marketed.

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