**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

# Tamoxifen Teva 20 mg

**Film-coated tablets**

**Composition:**
Each tablet contains:
Tamoxifen (as citrate) 20 mg

For information about inactive ingredients and allergens, see section 2 - 'Important information about some of this medicine's ingredients', and section 6, 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

**This medicine is not intended for children.**

## 1. What is this medicine intended for?

For treatment of breast cancer.

**Therapeutic group:** Anti-oestrogens.

Oestrogen is a natural substance in your body known as a 'sex hormone'. Some breast cancers need oestrogen to grow. Tamoxifen Teva 20 mg works by blocking the effects of oestrogen.

## 2. Before using the medicine

**Do not use this medicine if:**

- You are pregnant or think you might be pregnant (see the section 2 - 'Pregnancy and breastfeeding').
- You are sensitive (allergic) to tamoxifen or to any of the other ingredients the medicine contains (see section 6 - 'Additional information').
- You are taking anastrozole.
- You have had problems with blood coagulation in the past with the cause not known.
- Someone in your family has had problems with blood coagulation with the cause not known.
- Your doctor has told you that you have a hereditary disease that increases the risk of blood clots.

Do not take the medicine if any of these conditions applies to you. If you are not sure, talk to your doctor or pharmacist before taking the medicine.

**Special warnings about using this medicine**
Consult your doctor before taking Tamoxifen Teva 20 mg.

- In a delayed breast reconstruction operation (weeks to years after the primary breast operation when your own tissue is moved to shape a new breast), Tamoxifen Teva 20 mg may increase the risk of the formation of blood clots in the small vessels of the tissue flap, which may lead to complications.
- If you have a history of hereditary angioedema, you should know that Tamoxifen Teva 20 mg may worsen the symptoms of hereditary angioedema. If you experience swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing, contact a doctor immediately.

Serious skin reactions
Serious skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) have been reported while taking Tamoxifen Teva 20 mg. Stop using Tamoxifen Teva 20 mg and contact a doctor immediately if you notice signs related to these reactions (see section 4).

**Children and adolescents**
This medicine is not intended for children.

**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.

**Drug interactions**
**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements tell your doctor or pharmacist.** This is because Tamoxifen Teva 20 mg can affect the way some other medicines work and some medicines can have an effect on Tamoxifen Teva 20 mg. In particular, tell your doctor or pharmacist if you are taking:

- Oral contraceptives
- Hormone replacement therapy (HRT)
- Antidepressants (e.g. paroxetine, fluoxetine)
- Bupropion (used as an antidepressant or aid to smoking cessation)
- Quinidine (used in the treatment of cardiac arrhythmia)
- 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 to treat tuberculosis (TB)
- Medicines known as "aromatase inhibitors" that are used to treat breast cancer. These medicines include anastrozole, letrozole and exemestane.

**Contraception**
Women who can become pregnant should use adequate non-hormonal contraception (e.g., barrier contraception) during treatment with Tamoxifen Teva 20 mg and for an additional 9 months after stopping treatment.

**Pregnancy and breastfeeding**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

**Pregnancy**

- Do not take Tamoxifen Teva 20 mg if you are pregnant, because it may affect your unborn baby.
- Avoid becoming pregnant and breastfeeding whilst taking Tamoxifen Teva 20 mg and for 9 months after stopping treatment.
- As you should not become pregnant when taking Tamoxifen Teva 20 mg, consult your doctor on what contraceptive methods are appropriate, as the effectiveness of some contraceptives may be affected as a result of use of Tamoxifen Teva 20 mg.
- You should see your doctor immediately if you think you may have become pregnant after starting to take Tamoxifen Teva 20 mg.

**Breastfeeding**
Consult your doctor before taking Tamoxifen Teva 20 mg if you are breastfeeding.

**Driving and using machines**
Tamoxifen Teva 20 mg is not likely to affect your ability to drive or use any tools or machines. However, people who take Tamoxifen Teva 20 mg have reported tiredness and therefore caution should be observed when driving or operating machinery while such symptoms persist.

**Important information about some of this medicine's ingredients**
This medicine contains less than 23 mg of sodium per tablet and is therefore considered 'sodium free.'

## 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
**Do not exceed the recommended dose.**

**How to use the medicine:**

- Do not crush or chew the tablet in order to limit exposure to the active ingredient due to concerns about side effects. Swallow the tablets with a large amount of water.
- The tablet may be split at the score line.

**If you have accidentally used a higher dose**
If you have accidentally used a higher dose or if a child has accidentally swallowed some medicine, contact the doctor or pharmacist immediately.

**If you forget to take the medicine**

- If you forget to take the medicine at the scheduled time, take a dose 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.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**
**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## 4. Side effects

Like with all medicines, using Tamoxifen Teva 20 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

**Stop taking Tamoxifen Teva 20 mg 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 such as swelling of the calf or leg, chest pain, being short of breath or suddenly feeling weak.
- Symptoms of a stroke, including sudden onset of the following: weakness or paralysis of the arms or legs, being unable to move the arms or legs, sudden difficulty speaking, walking, or holding things, or difficulty thinking. These symptoms are caused by a reduced blood supply in the brain.
- Difficulty breathing.
- Swelling of the face, lips, tongue or throat which may make it difficult to swallow.
- Swelling of the hands, feet or ankles.
- Allergic rash (called hives or urticaria).
- Serious rash with blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. This serious rash can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)). These side effects occur rarely.
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing (angioedema). Tamoxifen Teva 20 mg may cause or worsen symptoms of hereditary angioedema.

**Tell your doctor straight away if the following side affects appear:**

- 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. Sometimes these effects are serious and could include cancer. They can happen during or after treatment with Tamoxifen Teva 20 mg.

**Additional side effects:**
**Very common (may affect more than 1 in 10 patients)**
• Nausea • Fluid retention • Skin rash • Hot flushes • Tiredness • Depression

**Common (may affect up to 1 in 10 patients)**
• Anaemia (a blood problem which means you have too few red blood cells) • Changes in vision due to cataracts (clouding of the lens of the eye) or changes to the retina of your eye • Increased amounts of fats in your blood (shown by blood tests) • Allergic reactions • Leg cramps • Changes in the womb (including changes to its lining and benign growths) • Headache • Dizziness • 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 patients)**

- 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 (may cause moderate to sever pain in the stomach)
- Changes in the amount of calcium in your blood (the signs are feeling very sick, being sick a lot or being thirsty). **Contact your doctor if this happens**, because you may be required to take blood tests
- Inflammation of the lungs (the symptoms may be feeling short of breath, coughing)
- Liver cirrhosis (problems with your liver)

**Rare (may affect up to 1 in 1,000 patients)**

- Severe blood problems. This can make you bruise more easily, get serious infections, or feel very tired or breathless
- Changes to the cornea of the eye
- Problems with the nerve that connects your retina to your brain
- Swelling of the optic nerve
- Severe liver diseases that caused death in certain cases. Severe liver diseases that 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
- Non-cancerous mass in the inner lining of the vagina (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)

**Very rare (may affect up to 1 in 10,000 patients)**

- Inflammation of the skin characterized by rash or erythema, very often on areas of the body exposed to light (cutaneous lupus erythematosus)
- A skin disease characterised by skin blisters in areas of the body exposed to the light due to the increased liver production of pigments (porphyrins)
- Skin rash involving redness, swelling, and/or blistering (like severe sunburn) of the skin after receiving radiation therapy (radiotherapy)

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

## 5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor!

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- **Store in the original package to protect from light.**
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

## 6. Additional information

In addition to the active ingredient, this medicine also contains: Mannitol, Sodium starch glycolate, Povidone, Hypromellose, Magnesium stearate, Colloidal silicon dioxide,Titanium dioxide, Polyethylene glycol 400.

**What the medicine looks like and contents of the pack:**
White, round, biconvex, film-coated tablet, with a scoreline and with the number "20" marked above the line and the letter "T" below on the reverse side of the tablet.

Package sizes: 10, 30, 100, 250 tablets. Not all pack sizes may be marketed.

**Registration holder's name and address:**
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

**Revised in January 2022 according to MOH guidelines.**

**Registration number of the medicine in the Ministry of Health's National Drug Registry:**
142.98.33084

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