PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Anastrozole Teva Tablets

Composition

Each tablet contains:

Anastrozole 1 mg

For information regarding inactive ingredients and allergens, see the subsection "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

This medicine is not intended for children and adolescents.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of advanced breast cancer in post-menopausal women.

Therapeutic group

Aromatase enzyme inhibitors. Anastrozole Teva acts by reducing the amount of the hormone called estrogen produced by your body. Anastrozole Teva does that by blocking a natural substance (an enzyme) in your body called aromatase.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient anastrozole or to any of the other ingredients this medicine contains (please see section 6 – "Additional information")
- You are pregnant or breastfeeding (see the subsection "Pregnancy and breastfeeding")

Special warnings regarding the use of the medicine

Before the treatment with Anastrozole Teva, tell the doctor if:

- You still have menstrual periods and have not yet gone through menopause
- You are taking a medicine that contains tamoxifen or medicines that contain estrogen (see the subsection "Drug interactions")
- You are suffering or have suffered in the past from any condition that affects bone strength (osteoporosis or osteopenia). Anastrozole Teva lowers the levels of female hormones and this may cause a loss of the mineral content of bones, which may decrease their strength. During the treatment, you may have to undergo bone density tests. Your doctor can prescribe you a medicine to prevent or treat bone loss. Women with severe osteoporosis are not suitable for medical treatment with anastrozole.
- You have liver or kidney problems
- You suffer from heart problems or have had a stroke

Additional warnings

- In the event that you go to a hospital you must inform the medical staff that you are taking Anastrozole Teva

Children and adolescents

Do not give Anastrozole Teva to children and adolescents.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Do not take Anastrozole Teva if you are already taking one of the following medicines:

- Certain medicines used to treat breast cancer (selective estrogen receptor modulators), for example medicines that contain tamoxifen, because these medicines may impair the efficacy of Anastrozole Teva
- Medicines that contain estrogen, such as hormone replacement therapy preparations

Tell the doctor or pharmacist if you are taking:

- Medicines belonging to the LHRH analogue group, such as: gonadorelin, buserelin, goserelin, leuprorelin and triptorelin. These medicines are used to treat breast cancer, to treat certain gynecological conditions and to treat infertility

Use of the medicine and food

You can take Anastrozole Teva before, during, or after eating.

Pregnancy and breastfeeding

Do not use Anastrozole Teva if you are pregnant or breastfeeding. Stop taking Anastrozole Teva if you find out that you are pregnant and consult the doctor.

If you are planning to become pregnant, consult the doctor or pharmacist before using the medicine.

Driving and operating machinery

This medicine is not expected to impair the ability to drive a vehicle or to operate tools or machinery. However, there are patients who may sometimes feel weakness or sleepiness during the treatment with Anastrozole Teva. If you experience these effects, consult the doctor or a pharmacist.

Important information about some of the ingredients of the medicine

The tablets contain lactose. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to certain sugars, please refer to the doctor before taking Anastrozole Teva.

Anastrozole Teva contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use the preparation according to the doctor's instructions.
- Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
- The dosage and treatment regimen will be determined only by the doctor.
- The accepted dosage for adults is one tablet per day.

Do not exceed the recommended dose.

This medicine should be used at set intervals as determined by the treating doctor.

Method of use

- Try to take the tablet at the same time each day.
- No information is available regarding chewing and pulverizing the tablets. Do not halve the tablets in the absence of a score line.
- The tablet should be swallowed whole with a glass of water.
- Continue taking the medicine as long as the doctor instructs you to. This is a long-term treatment and you may have to take it for several years.

If you have taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed this medicine, refer immediately to a doctor or to a hospital emergency room and take the package of the medicine with you.

If you have forgotten to take the medicine

If you forgot to take a dose, take the next dose as usual. Do not take a double dose (two doses at once) to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health and/or you feel better, do not stop the treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Anastrozole Teva tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Side effects that require special attention. Discontinue use and refer to a doctor immediately if the following severe side effects occur:

Common side effects (effects that occur in 1-10 out of 100 patients):

- Allergic reactions (hypersensitivity) including the face, lips or tongue

Rare side effects (effects that occur in 1-10 out of 10,000 patients):

- Rare skin inflammation that may include red patches or blisters (erythema multiforme)

Very rare side effects (effects that occur in less than 1 patient out of 10,000 patients):

- An extremely severe skin reaction (Stevens-Johnson syndrome) with ulcers or blisters
- Allergic reactions (hypersensitivity) accompanied by swelling of the throat, which may cause swallowing or breathing difficulties (angioedema)

Additional side effects

Very common side effects – occur in more than 1 out of 10 patients:

- Headache
- Hot flashes
- Nausea
- Skin rash
- Joint stiffness or pain
- Joint inflammation (arthritis)
- Weakness
- Bone loss (osteoporosis)
- Depression

Common side effects – occur in 1-10 out of 100 patients:

- Loss of appetite
- Raised or high levels of cholesterol in the blood which are seen in blood tests
- Feeling sleepy
- Carpal tunnel syndrome, manifested by tingling, pain, coldness and weakness in different parts of the hand
- Tickling, tingling or numbness of the skin, loss/distortion of the sense of taste
- Diarrhea
- Vomiting
- Changes in liver function that are seen in blood tests
- Thinning of the hair (hair loss)
- Bone pain
- Vaginal dryness
- Vaginal bleeding (usually in the first few weeks of treatment – if the bleeding continues, refer to the doctor)
- Muscle pain

Uncommon side effects – occur in 1-10 out of 1,000 patients:

- Changes in certain blood test results for liver function, such as gamma-GT and bilirubin tests
- Hepatitis
- Hives or urticaria (itchy skin rash)
- Trigger finger – a condition in which the ability to straighten the thumb or finger is impaired
- Raised blood calcium levels. If you have nausea, vomiting and a feeling of thirst, you should inform the doctor. The doctor will consider performing blood tests in order to check your blood calcium levels

Rare side effects – occur in 1-10 out of 10,000 patients:

- Inflammation of small blood vessels in the skin (capillaries) causing redness or the appearance of purple color in the skin. Very rare symptoms may occur: joint pain, abdominal pain and kidney pain. This phenomenon is called "Henoch-Schönlein purpura"

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- Dry eye.
- Lichenoid eruption – small, red and itchy skin lesions.
- Inflammation of the tendon (the connective tissue that connects the muscle and bone).
- Rupture of the tendon (the connective tissue that connects the muscle and bone).
- Memory impairment.

Effect on the bones

Anastrozole Teva decreases the level of estrogen in the body, which may cause loss of bone mineral content and a reduction in bone strength. In some cases this can result in fractures. Your doctor will manage the risks according to the treatment guidelines for bone health in menopausal women. You should discuss the risks and treatment options with the doctor.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store in a dry place below 25°C.

Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, sodium starch glycolate, povidone, hypromellose (hydroxypropyl methylcellulose), magnesium stearate, titanium dioxide, polyethylene glycol

What does the medicine look like and what are the contents of the package:

A round, white-off-white film coated tablet, embossed with the number "93" on one side of the tablet and "A10" on the other side.

Package sizes: 30 tablets in a tray (blister) package.

Name and address of the manufacturer and license holder:

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

Revised in September 2025.

Registration number of the medicine in the national drug registry of the Ministry of Health:

141.32.31760

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