PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Exemestane Teva 25 mg
Film-coated Tablets

Composition
Each film-coated tablet contains:
Exemestane 25 mg.
For a list of the inactive ingredients, please see section 6, and also see section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.
This medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR?

Exemestane Teva 25 mg is used to treat early-stage hormone-dependent breast cancer in postmenopausal women after they have already completed 2-3 years of treatment with the medicine tamoxifen.
In addition, Exemestane Teva 25 mg is used to treat advanced hormone-dependent breast cancer in postmenopausal (naturally or induced) women, whose disease progressed after a single hormonal treatment or after several hormonal treatments (anti-estrogenic).

Therapeutic group:
Steroidal inhibitors of the aromatase enzyme, anti-neoplastic (anti-cancer) agents.
Exemestane Teva 25 mg belongs to a group of aromatase inhibitors - the enzyme needed, especially in postmenopausal women, to produce the female sex hormones, estrogens.
Reduction in estrogen levels in the body is a way of treating hormone-dependent breast cancer.

2. BEFORE USING THE MEDICINE

Do not use the medicine if you are:
- Sensitive (allergic) or have been sensitive in the past, to the active ingredient (exemestane) or to any of the additional ingredients contained in the medicine (for further information please see section 6)
- Pregnant, may be pregnant or breastfeeding
- Before menopause (you still have monthly periods)

Special warnings regarding use of the medicine
Before treatment with Exemestane Teva 25 mg tell the doctor if:
- You have problems with your liver or kidneys.
- You are suffering, or have suffered in the past, from an ailment that affects bone strength. The doctor may want to perform bone density tests before and during Exemestane Teva 25 mg treatment. This is because medicines of this class lower the levels of female hormones, which may lead to loss of mineral content of the bones, which may reduce their strength.
- **Tests that must be performed before using the medicine:**
  - The doctor may take blood samples to make sure you have reached menopause.
  - Routine testing of your vitamin D level. In the early stages of breast cancer, it is possible that your vitamin D level will be very low. The doctor will give you a vitamin D supplement if your vitamin D level is lower than normal.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Especially if you are taking:
- Medicines containing estrogen
- Rifampicin (an antibiotic)
- Phenytoin or carbamazepine (anticonvulsants used to treat epilepsy)
- Herbal preparations that contain Hypericum (St. John's wort)

Do not take Exemestane Teva 25 mg at the same time as hormone replacement therapy (HRT).

Use of the medicine and food
The medicine should be taken after a meal.

Pregnancy and breastfeeding
- Do not take Exemestane Teva 25 mg if you are pregnant or breastfeeding.
- If you are pregnant or think you might be pregnant, tell the doctor.
- If there is any possibility that you may become pregnant, consult with the doctor in regards to contraception.

Driving and operating machinery
If you feel drowsy, dizzy or weak while taking Exemestane Teva 25 mg, do not drive or operate machinery.

Important information about some of the ingredients of the medicine
The medicine Exemestane Teva 25 mg contains sodium. There is less than 23 mg sodium per tablet, so the medicine is essentially considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
One 25 mg tablet, once a day, orally, after a meal, at around the same time every day. Your doctor will determine the treatment regimen and duration.

Do not exceed the recommended dose.
- There is no information regarding crushing/halving/chewing Exemestane Teva 25 mg tablets.
- Swallow the medicine with a little water.
- If you need to go to the hospital while taking Exemestane Teva 25 mg, inform the medical staff about the medicines you are taking.

If you accidentally took a higher dosage or if you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine at the designated time, do not take a double dose to compensate for the forgotten dose. Take the forgotten tablet as soon as you remember. If it is nearly time for the next dose, take the tablet at the usual time.

Adhere to the treatment regimen as recommended by the doctor.

Do not stop taking the medicine even if you feel well, unless so instructed by the doctor.

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

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

4. SIDE EFFECTS

As with any medicine, use of Exemestane Teva 25 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if you are suffering from:
Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts in the liver which cause yellowing of the skin. The symptoms include a general unwell feeling, nausea, jaundice (yellowing of the skin and eyes), itching, right-sided abdominal pain and lack of appetite.

Generally, Exemestane Teva 25 mg is well tolerated and the following side effects observed in patients treated with Exemestane Teva 25 mg are mainly mild or moderate. Most of the side effects are associated with estrogen deficiency (e.g., hot flushes).

Additional side effects
Very common side effects (may occur in more than 1 out of 10 users):
- Depression
- Difficulty falling asleep
- Headache
- Hot flushes
- Dizziness
- Nausea
- Excessive sweating
- Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- Tiredness
- Decreased number of white blood cells
- Abdominal pain
- Elevated level of liver enzymes
- Elevated level of a hemoglobin breakdown products in the blood
- Elevated level of the enzyme alkaline phosphatase in the blood due to liver damage
- Pain

Common side effects (may occur in up to 1 out of 10 users):
- Lack of appetite
- Carpal tunnel syndrome (a combination of "pins and needles", numbness and pain affecting all of the hand except the little finger) or prickling or tingling of the skin
- Vomiting, constipation, digestive problems, diarrhea
- Hair loss
- Skin rash, hives and itchiness
- Thinning of bones which might weaken their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Swollen hands and feet
- Decreased blood platelet count
- Feeling of weakness

Uncommon side effects (may occur in up to 1 out of 100 users):
- Hypersensitivity

Rare side effects (may occur in up to 1 out of 1,000 users):
- An eruption of small blisters on a specific area of the skin, when there is a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts in the liver which causes yellowing of the skin

Side effects of unknown frequency (effects whose frequency has not been determined):
- Low level of certain white blood cells in the blood

There may also be changes in the levels of certain blood cells (lymphocytes) and platelets circulating in your blood, especially in patients with a pre-existing lymphopenia (low level of lymphocytes in the blood).

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

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears 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 into the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Mannitol, Silicified Microcrystalline Cellulose, Copovidone Type A, Sodium Starch Glycolate (Type A), Crospovidone Type A, Hypromellose, Magnesium Stearate, Titanium Dioxide (E171), Macrogol 400.

What the medicine looks like and the contents of the package:
Round, film-coated, white to off-white tablet with the number "25" embossed on one side of the tablet, the other side of the tablet is plain.
Package sizes: 10, 14, 15, 20, 28, 30, 50, 60, 90, 98, 100 and 120 tablets in blister packs.
Not all package sizes may be marketed.

Name of License Holder and its Address:
Abic Marketing Ltd., P.O.B. 8077, Netanya

Name of Manufacturer and its Address:
Pharos Generics Ltd., Limassol, Cyprus

The leaflet was revised in July 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
149.95.33646

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