

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

This medicine is dispensed with a doctor's prescription only

Aromasin® Coated tablets 25 mg

The active ingredient and its quantity:

Each coated tablet contains:

exemestane 25 mg

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients", 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?

Aromasin® is used to treat hormone dependent early breast cancer in postmenopausal women after they have completed 2-3 years of treatment with the medicine tamoxifen. Additionally, Aromasin® is used for the treatment of hormone dependent advanced breast cancer in women in postmenopausal status (natural or induced) whose disease has progressed following a single hormonal (anti-estrogen) therapy or several hormonal therapies.

Therapeutic group: Steroidal inhibitors of the enzyme aromatase, anti-neoplastic (anti-cancer) agents.

Aromasin® belongs to a group of medicines known as aromatase inhibitors; aromatase is an enzyme required for the production of the female sex hormones, estrogens, especially in postmenopausal women. Reduction in estrogen levels in the body is a way of treating hormone dependent breast cancer.

2. Before using this medicine

⊠Do not use this medicine if:

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| <ul style="list-style-type: none">• you are or have previously been sensitive (allergic) to the active ingredient (exemestane) or to any of the other ingredients of this medicine. For additional information, please see section 6.• you are pregnant, likely to be pregnant or breastfeeding.• you are not postmenopausal (you are still having your monthly period). |
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Special warnings about using this medicine

ⓘ Before using Aromasin®, tell your doctor if:

- You have liver or kidney problems.
- You are suffering or have suffered in the past from a condition which affects the strength of your bones. Your doctor may want to perform bone mineral density tests before and during treatment with Aromasin®. This is because this class of medicines lowers the

levels of female sex hormones, which may lead to a loss of the mineral content of bones, which might decrease their strength.

! Tests and follow up

Tests to be performed before using the medicine:

- Your doctor may take blood samples from you to ensure you have reached menopause.
- Routine checking of vitamin D level. In the early stages of breast cancer, your vitamin D level may be very low. The doctor will give you a vitamin D supplement if your vitamin D level is below normal.

! Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines containing estrogen
- rifampicin (an antibiotic)
- phenytoin or carbamazepine (anticonvulsants used to treat epilepsy)
- herbal preparations containing Hypericum (St. John's Wort)

Aromasin[®] should not be taken at the same time with hormone replacement therapy (HRT).

! Using this medicine and food

Swallow the medicine after a meal.

! Pregnancy and breastfeeding

Do not take Aromasin[®] 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 regarding contraception.

! Driving and using machines

If you feel drowsy, dizzy or weak while taking Aromasin[®], you must not drive or operate machines.

! Important information about some of this medicine's ingredients

- Aromasin[®] contains sucrose. If you have been told by the doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.
- Aromasin[®] contains a small amount of sodium, less than 1 mmol (23 mg), therefore it is considered "sodium free".
- Aromasin[®] contains a small amount of methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). If this should happen, contact your doctor.

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.

The recommended dosage is usually:

One 25 mg tablet daily taken orally after a meal, at approximately the same time each day. Your doctor will determine the manner and duration of treatment.

Do not exceed the recommended dose!

There is no information regarding crushing/ splitting/ chewing Aromasin® tablets

- Swallow the medicine with a little water.
- If you need to go to the hospital while taking Aromasin®, inform the medical staff about the medicines you are taking.

If you have accidentally taken a higher dose or if you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the designated time, do not take a double dose to make up 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 as recommended by your doctor.

Do not stop taking the medicine even if you feel well, unless instructed to do so by the 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 Aromasin® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor immediately if you suffer from:

Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts of the liver which cause yellowing of the skin. Symptoms include a general unwell feeling, nausea, jaundice (yellowing of the skin and eyes), itching, right sided abdominal pain and loss of appetite.

Generally, Aromasin® is well tolerated and the following side effects observed in patients treated with Aromasin® are mainly mild or moderate. Most of the side effects are associated with a shortage of estrogen (such as hot flushes).

Additional side effects:

Very common side effects (may affect more than 1 in 10 users):

- Depression
- Difficulty falling asleep
- Headache
- Hot flushes
- Dizziness
- Nausea
- Increased sweating
- Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- Tiredness
- A reduction in the number of white blood cells
- Abdominal pain
- Elevated level of liver enzymes
- Elevated level of hemoglobin breakdown in the blood
- High level of alkaline phosphatase enzyme in the blood due to liver damage
- Pain

Common side effects (may affect up to 1 in 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 pricking or tingling of the skin
- Vomiting, constipation, indigestion, diarrhea
- Hair loss
- Skin rash, hives and itchiness
- Bone depletion which might decrease their strength (osteoporosis), leading in some cases to bone fractures (breaks or cracks)
- Swollen hands and feet
- A reduction in blood platelet count
- Feeling of weakness

Uncommon side effects (may affect up to 1 in 100 users):

- Hypersensitivity

Rare side effects (may affect up to 1 in 1,000 users):

- A breakout of small blisters in a certain area of the skin in a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts of the liver which causes yellowing of the skin

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Low level of certain white blood cells in the blood

It is possible that there may be changes in the level 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 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.

Side effects may be reported 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, or by using this link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! To avoid 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) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to discard medicines no longer used. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Sucrose; mannitol; microcrystalline cellulose; titanium dioxide; hypromellose; sodium starch glycollate; crospovidone; magnesium carbonate, light; polyvinyl alcohol; magnesium stearate; macrogol 6000; silica, colloidal hydrated; polysorbate 80; simethicone emulsion; methyl-p-hydroxybenzoate

What the medicine looks like and contents of the pack:

Aromasin® are round, biconvex, off-white (cream colored), coated tablets marked with “7663” on one side.

Aromasin® is available in blister packs. Each pack contains 15, 30, 60, 90 or 120 tablets. Not all pack sizes may be marketed.

Registration holder’s name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach, 46725

Manufacturer’s name and address: Pfizer Italia S.r.l., 63100 Ascoli piceno, Italy

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 119-48-30005.

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