

AROMASIN[®] TABLET

Exemestane (25 mg)

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What Aromasin is used for

Aromasin is used to treat hormone dependent early breast cancer in post-menopausal women after they have completed 2-3 years of treatment with the medicine tamoxifen.

Aromasin is indicated for the second- and third-line treatment of advanced breast cancer (ABC) in women with post-menopausal status whose disease has progressed following anti-estrogen therapy alone or following multiple hormonal therapies respectively.

How Aromasin works

Aromasin is an irreversible, steroidal aromatase inhibitor. It interferes with the normal estrogen production by blocking the enzyme aromatase, which is used to convert androgens (hormones produced by adrenal glands) into estrogen. It thereby helps lower estrogen production in postmenopausal women. Estrogen deprivation hampers the growth of hormone dependent breast cancer.

Before you use Aromasin

- When you must not use it

If you are or have previously been allergic (hypersensitive) to exemestane (the active ingredient in Aromasin) or any of the other ingredients of Aromasin. See section "Product description" for full list of other ingredients.

Pregnancy and lactation

Do not take Aromasin if you are pregnant, trying to get pregnant or think you may be pregnant because it may cause harm to the fetus. In animal reproductive studies, exemestane demonstrated some toxic effects.

Do not take Aromasin if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if you have a history or are suffering from any condition, which affects the strength of your bones. Your doctor may want to measure your bone density before and during the treatment of Aromasin. This is because medicines of this class lower the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength.

Routine checking of your vitamin D level will also be made before treatment, as your level may be very low in the early stages of breast cancer. You will be given vitamin D supplement if your levels are below normal.

Inform your doctor if you have not already been through the menopause because you should not use Aromasin tablets if you are still having your monthly period.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Aromasin should not be given at the same time as hormone replacement therapy (HRT) especially estrogen containing medicines.

How to use Aromasin

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adult and Elderly

The recommended dose of Aromasin is one 25 mg tablet to be taken once daily.

Liver or Kidney Insufficiency

No dose adjustments are required for those with liver or kidney insufficiency.

Children

Aromasin is not suitable for use in children.

- When to use it

Use as directed by your doctor or pharmacist.

Aromasin tablets should be taken by mouth after a meal at approximately the same time each day. Your doctor will tell you how to take Aromasin.

- How long to use it

Continue taking Aromasin for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Do not take a double dose to make up for a forgotten tablet.

If you forget to take your tablet, take it as soon as you remember. If it is nearly time for the next dose, take it at the usual time.

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- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Show them the pack of Aromasin tablets.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Aromasin.

Tell your doctor immediately if you become pregnant while taking this medication.

If you need to go to the hospital whilst taking Aromasin, let the medical staff know what medication you are taking.

- Things you must not do

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

Do not take any new medicines without consulting your doctor.

Do not give Aromasin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Aromasin can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In general, Aromasin is well tolerated and the following side effects observed in people treated with Aromasin are mainly mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes).

The side effects are listed below:

- Hypersensitivity
- Difficulty sleeping
- Headache
- Hot flushes
- Increased sweating
- Muscle and joint pain (including back pain, joint inflammation and stiffness)
- Tiredness
- Depression
- Dizziness
- Stomach ache
- Pain
- Elevated level of liver enzymes
- Inflammation of liver
- Hepatitis cholestatic (flow of bile from liver stops or slows)
- Acute generalised exanthematous pustulosis (drug related reaction characterized by a small, primarily non-follicular, sterile skin pustules arising within large areas of red swollen skin usually within two weeks)
- Elevated level of bilirubin in blood
- Elevated level of alkaline phosphatase (a blood enzyme) in the blood
- Anorexia (eating disorder)
- Carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger)
- Finger gets stuck in a bent position (Trigger Finger)
- Tendon pain and swelling, as these may be signs of tendon rupture (complete or partial tear of the tendon), tendonitis (tendon inflammation) or tenosynovitis (inflammation of the tendon sheath that surrounds the tendon)
- Vomiting (being sick)
- Nausea
- Constipation
- Indigestion
- Diarrhoea

- Skin rash
- Hair loss
- Thinning of bones which might decrease their strength (osteoporosis)
- Leading to bone fractures (breaks or cracks) in some cases
- Swollen hands and feet
- Paraesthesia (burning or prickling sensation)
- Urticaria (swelling of the skin)
- Pruritus (itching)

If you have any blood tests done, it may be noticed that there are changes in your liver function. Changes in the amount of certain blood cells (lymphocytes) may occur, especially in people with a pre-existing lymphopenia (reduced lymphocytes in the blood).

If any side effects get serious or if you notice any side effect not listed on this leaflet, please tell your doctor or your pharmacist as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Aromasin

- Storage

Store below 30°C.

Keep your tablets in the original pack. As with all medicines, keep them in safe place out of the reach and sight of children. Do not use Aromasin after expiry date which is stated on the outer carton and the blister after EXP. The expiry date refers to the last day of the month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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PLD-AROMASIN-1125

Product Description**- What it looks like**

Aromasin tablets are round, biconvex, off-white to slightly greyish sugar-coated tablets, about 6 mm diameter printed with numbers 7663 on one side in black ink.

Aromasin tablets are presented in aluminium foil/PVC-PVDC foil blister strips in cartons containing 30 or 90 tablets. Not all pack sizes may be marketed.

- Ingredients

- Active Ingredient
Exemestane

- Inactive ingredients

Mannitol, Hypromellose, Magnesium stearate, Silica colloidal hydrated, Crospovidone, Sodium starch glycolate (type A), Polysorbate 80, Microcrystalline cellulose, Purified water.

Coating agents: Hypromellose, Simethicone emulsion, Macrogols, Sucrose, Magnesium carbonate light, Titanium dioxide (E171), Methyl p-hydroxybenzoate, Polyvinyl alcohol.

- MAL number

MAL08111847AZ

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