

Aromasin® 25mg coated tablets

(exemestane)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Aromasin is and what it is used for

Your medicine is called Aromasin. Aromasin belongs to a group of medicines known as aromatase inhibitors. These drugs interfere with a substance called aromatase, which is needed to make the female sex hormones, oestrogens, especially in postmenopausal women. Reduction in oestrogen levels in the body is a way of treating hormone dependent breast cancer.

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.

Aromasin is also used to treat hormone dependent advanced breast cancer in postmenopausal women when a different hormonal drug treatment has not worked well enough.

2 Before you take Aromasin

Do not take Aromasin:

- * 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 6 ("What Aromasin contains for") for full list of other ingredients.
- * if you have not already been through 'the menopause', i.e. you are still having your monthly period,
- * if you are pregnant, likely to be pregnant or breastfeeding.

Take special care with Aromasin

- * Before treatment with Aromasin, your doctor may want to take blood samples to make sure you have reached the menopause.
- * Before taking Aromasin, tell your doctor if you have problems with your liver or kidneys.
- * 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 drugs 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.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

The following medicines should be used cautiously when taking Aromasin. Let your doctor know if you are taking medicines such as:

- * rifampicin (an antibiotic),
- * carbamazepine or phenytoin (anticonvulsants used to treat epilepsy),
- * the herbal remedy St Johns Wort (*Hypericum perforatum*), or preparations containing it.

Pregnancy and breast-feeding

Do not take Aromasin if you are pregnant or breastfeeding.

If you are pregnant or think you might be, tell your doctor.

Discuss contraception with your doctor if there is any possibility that you may become pregnant.

Driving and using machines

If you feel drowsy, dizzy or weak whilst taking Aromasin, you should not attempt to drive or operate machinery.

Important information about some of the ingredients of Aromasin

- * If you have previously been told that you have intolerance to some sugars, contact your doctor before taking this medicine. Aromasin tablets contain sucrose (a type of sugar), which may cause a problem in a small number of patients with hereditary intolerance to some sugars (glucose-galactose malabsorption, fructose intolerance or sucrose-isomaltase insufficiency).
- * Aromasin contains a small amount of methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed), if this should happen please contact your doctor.

3 How to take Aromasin

Adults and the elderly

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 and for how long. The recommended dose is one 25 mg tablet daily.

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

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

Children

Aromasin is not suitable for use in children.

If you take more Aromasin than you should

If too many tablets are taken by accident, contact your doctor at once or go straight to the nearest hospital casualty department. Show them the pack of Aromasin tablets.

If you forget to take Aromasin

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.

4 Possible side effects

Like all medicines, Aromasin can cause side effects, although not everybody gets them. In general, Aromasin is well tolerated and the following side effects observed in patients 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).

Very common side effects, (affecting more than 1 person in 10)

- * Difficulty sleeping
- * Headache
- * Hot flushes
- * Feeling sick
- * Increased sweating
- * Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- * Tiredness

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Common side effects, (affecting between 1 to 10 people in 100)

- * Loss of appetite
- * Depression
- * Dizziness, carpal tunnel syndrome (a combinations of pins and needles, numbness and pain affecting all of the hand except the little finger)
- * Stomach ache, vomiting (being sick), 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
- * Pain, swollen hands and feet

Uncommon side effects, (affecting between 1 to 10 people in 1000)

- * Drowsiness
- * Muscle weakness

Inflammation of the liver (hepatitis) may occur. Symptoms include feeling generally unwell, nausea, jaundice (yellowing of the skin and eyes), itching, right sided abdominal pain and loss of appetite. Contact your doctor promptly if you think you have any of these symptoms.

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) and platelets circulating in your blood may occur, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood).

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

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Aromasin

Store in the original package.
Keep this medicine out of the sight and reach of children.

Do not use Aromasin after the expiry date which is stated on the carton and blister after (EXP). The expiry date refers to the last day of that month.

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.

6 Further information

What Aromasin contains

The active substance is exemestane. Each coated tablet contains 25 mg exemestane.

The other ingredients are:

silica colloidal hydrated, crospovidone, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycollate (Type A), polysorbate, polyvinyl alcohol, simeticone, macrogol, sucrose, magnesium carbonate light, methyl parahydroxybenzoate (E218), cetyl esters wax, talc, carnauba wax, ethyl alcohol, shellac, titanium oxide (E171) and iron oxides (E172).

What Aromasin looks like and contents of the pack

Aromasin is a round, biconvex, off-white, coated tablet marked 7663 on one side. Aromasin is available in blister packs of 30 tablets.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Pfizer Italia S.r.l., Localita Marino del Tronto 63100 Ascoli Piceno (AP) Italy.

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Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.