

PACKAGE LEAFLET: INFORMATION FOR THE USER

AROMASIN 25 mg coated tablets (exemestane)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Aromasin is and what it is used for
2. What you need to know before you take Aromasin
3. How to take Aromasin
4. Possible side effects
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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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AROMASIN

Do not take Aromasin

- if you are or have previously been allergic to exemestane (the active ingredient in Aromasin) or any of the other ingredients of this medicine (listed in section 6).
- 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 breast-feeding.

Warnings and precautions

- Before treatment with Aromasin, your doctor may want to take blood samples to make sure you have reached the menopause.
- 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.
- 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.

Other medicines and Aromasin

Please tell your doctor if you are taking, have recently taken or might take 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 John's Wort (*Hypericum perforatum*), or preparations containing it.

Pregnancy and breast-feeding

Do not take Aromasin if you are pregnant or breast-feeding.

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.

Aromasin contains sucrose and methyl parahydroxybenzoate

- 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 sucrase-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

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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.

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

Use in 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.

If you stop taking Aromasin

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

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).

Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts of the liver which cause yellowing of the skin (cholestatic 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 to seek urgent medical advice if you think you have any of these symptoms.

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

- Depression
- Difficulty sleeping
- Headache
- Hot flushes
- Dizziness
- Feeling sick
- 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 a hemoglobin breakdown in the blood
- Elevated level of a blood enzyme in the blood due to liver damage
- Pain

Common side effects (may affect up to 1 in 10 people):

- Loss of appetite
- Carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger) or tingling/prickling of the skin
- Stomach ache, vomiting (being sick), constipation, indigestion, diarrhoea
- Hair loss
- Skin rash, hives and itchiness
- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Pain, swollen hands and feet
- A reduction in the number of platelets in the blood
- Muscle weakness

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

- Hypersensitivity

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

- A breakout of small blisters on an area of the skin in a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts of the liver which cause yellowing of the skin

Not known side effect (frequency cannot be estimated from the available data):

- Low level of certain white blood cells in the blood

Changes in the amount of certain blood cells (lymphocytes) and platelets circulating in your blood, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood) may also be seen.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE AROMASIN

- Keep this medicine out of the sight and reach of children.
- Do not use Aromasin after the 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.
- This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER 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 glycolate (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 15, 20, 30, 90, 100 and 120 tablets.
Not all pack sizes will be marketed.

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Manufacturer

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