PACKAGE LEAFLET: INFORMATION FOR THE USER

AROMASIN® 25MG COATED TABLETS
(exemestane)

Your medicine is available using the above name but will be referred to as Aromasin throughout this leaflet.

Aromasin 25mg coated tablets are marketed in the UK as Exemestane 25mg coated tablets. The blister strip may state both names.

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.

What is 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
5. How to store Aromasin
6. Contents of the pack and other information

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 medicines 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

- Talk to your doctor, pharmacist or nurse before taking Aromasin.
- 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 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.

Other medicines and Aromasin
Tell your doctor or pharmacist 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, sodium and methyl parahydroxybenzoate

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
- 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 patients
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 25mg 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

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.

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 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 haemoglobin 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
- 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
- Swollen hands and feet
- A reduction in the number of platelets in the blood
- Feeling of weakness

Uncommon: side effects may affect up to 1 in 100 people
- Hypersensitivity

Rare: 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 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

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 that month.

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 25mg 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, shellac, ethyl alcohol, titanium oxide (E171) and iron oxides (E172).

What Aromasin looks like and contents of the pack
Aromasin are round, biconvex, off-white, coated tablets marked '7663' on one side.

Aromasin is available in blister packs of 30 tablets.

Manufacturer
Manufactured by: Pfizer Italia S.r.l.,
Localita Marino del Tronto, 63100 Ascoli Piceno, Italy.

Procured from within the EU and Repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

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Aromasin® is a registered trademark of
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This medicinal product is authorised in the member states of the EEA under the following names:

Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Portugal, Sweden, United Kingdom:	Aromasin
France:	Aromasine
Spain:	Aromasil

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