

Exemestane 25 mg Film-coated Tablets

(Exemestane)

Ref: 184/001/190716/1/F

PACKAGE LEAFLET: INFORMATION FOR THE USER

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, pharmacist or nurse.
- * 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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Exemestane tablet is and what it is used for
- 2 What you need to know before you take Exemestane tablets
- 3 How to take Exemestane tablets
- 4 Possible side effects
- 5 How to store Exemestane tablets
- 6 Contents of the pack and other information

1 What Exemestane tablet is and what it is used for

Exemestane 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.

Exemestane 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.

Exemestane 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 Exemestane tablets.

Do not take Exemestane tablets

- * if you are or have previously been allergic (hypersensitive) to exemestane or any of the other ingredients of Exemestane tablets. See section 6 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.

Warnings and precautions

- * Exemestane tablets contain a forbidden substance which is being able to provide a positive result in a doping control tests.
- * Before treatment with Exemestane, your doctor may want to take blood samples to make sure you have reached the menopause
- * Before taking Exemestane, 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 and/or 25 hydroxy vitamin D levels before and during the treatment of Exemestane. 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 Exemestane Tablets

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

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

Tell your doctor if you are taking any of the following medicines:

- * rifampicin (an antibiotic),
- * drugs used to treat epilepsy (carbamazepine or phenytoin),
- * the herbal medicines use as anti-depressant (St Johns Wort, (Hypericum perforatum)),

Exemestane Tablets with food, drink and alcohol

Exemestane Tablets should be taken after meal at approximately the same time each day.

Pregnancy, breast-feeding and fertility

Do not take Exemestane tablets 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3 How to take Exemestane tablets

Exemestane tablets should be taken after meal at approximately the same time each day.

Always take Exemestane tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one 25 mg tablet daily.

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

Use in children

Exemestane tablets is not suitable for use in children.

If you take more Exemestane Tablets 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 Exemestane tablets.

If you forget to take Exemestane Tablets

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 Exemestane Tablets

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 medicine, ask your doctor or pharmacist.

Exemestane 25 mg Film-coated Tablets (Exemestane)

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4 Possible side effects

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

Exemestane tablets are well tolerated and the following side effects observed in patients treated with Exemestane tablets are mainly mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes)."

The following side effects have been reported by people taking Exemestane tablets.

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

- * headache
- * hot flushes
- * feeling sick
- * increased sweating
- * muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- * fatigue
- * insomnia
- * nausea

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, diarrhea
- * 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
- * whitish raised patches in skin, intense itching

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

- * drowsiness
- * muscle weakness
- * decrease in the number of white blood cells
- * allergic reaction
- * sleepiness
- * hepatitis, liver inflammation due to blocked liver channels, increased liver enzymes, increased levels of bilirubin in the blood increased levels of alkaline phosphatase in the blood
- * sudden skin eruption due to the drug

Rare (affect up to 1 in 1,000 people)

- * Abnormal decrease in the number of platelets in the blood

Not Known (frequency cannot be estimated from the available data)

- * Changes in the amount of certain blood cells (lymphocytes) in your blood

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 of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Exemestane Tablets

- * Keep out of the sight and reach of children.
- * Do not use Exemestane Tablets after the expiry date which is stated on the Carton and blister (EXP, e.g. mm/yyyy). The expiry date refers to the last day of that month e.g. mm/yyyy.
- * This medicinal product 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 Exemestane Tablets contains

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

The other ingredients are:

Core: Mannitol, cellulose microcrystalline, crospovidone, sodium starch glycolate (Type A), hypromellose E5, polysorbate 80, colloidal anhydrous silica and magnesium stearate.

Coating:

Hypromellose 6cp (E464), titanium dioxide (E171) and macrogol 400.

What Exemestane tablets looks like and contents of the pack

Exemestane Tablets are white to off-white, round, biconvex film coated tablets debossed with 'E25' on one side and plain on the other.

Exemestane 25 mg Tablets are available in the White opaque blister packs of 30 Tablets.

The Parallel Product Authorisation Holder is:

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Repackaged by:

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

The manufacturer is:

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Or

CEMELOG-BRS Ltd. H-2040 Budaors, Vasut u. 13 Hungary.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

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for help.