

Package leaflet: Information for the user
Exemestane 25 mg Film-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, 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 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 to exemestane 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 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.
- 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.
- 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 or might take any other medicines, including medicines obtained without a 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 remedy St Johns Wort, (*Hypericum perforatum*), or preparations containing it.

Exemestane Tablets with food, drink and alcohol

Exemestane Tablets should be taken after a 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

Adults and the elderly

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

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

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.

4. Possible side effects

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

Exemestane tablets is 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)."

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 combinations 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 number of platelets in 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 (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.

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 after EXP. The expiry date refers to the last day of that month.
- 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, croscopovidone, sodium starch glycolate (Type A), hypromellose E5, polysorbate 80, colloidal anhydrous silica, magnesium stearate

Coating:

Hypromellose 6cp (E464), titanium dioxide (E171), 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 PVC/PVdC-Alu blister packs of 15, 20, 28, 30, 90, 98, 100 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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