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 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 EXEMESTANE 25 MG FILM-COATED TABLETS IS AND WHAT IT IS USED FOR
Your medicine is called Exemestane. Exemestane 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.

Exemestane 25 mg film-coated tablets are 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 25 mg film-coated tablets are 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
Do not take Exemestane:
- If you are or have previously been allergic to Exemestane (the active ingredient in 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
- Talk to your doctor, pharmacist or nurse before taking Exemestane.
- Before treatment with Exemestane, 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 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 before and during the treatment of Exemestane. 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 Exemestane
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

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

The following medicines should be used cautiously when taking Exemestane. 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 Exemestane, 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 Exemestane, you should not attempt to drive or operate machinery.

Exemestane contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. HOW TO TAKE EXEMESTANE

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.

Exemestane should be taken by mouth after a 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, let the medical staff know what medication you are taking.

Use in children

Exemestane is not suitable for use in children.

If you take more Exemestane 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:**
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:
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, Exemestane is well tolerated and the following side effects observed in patients treated with Exemestane 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: 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: 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: may affect up to 1 in 100 people

- Hypersensitivity

Rare: may affect up to 1 in 1000 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.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EXEMESTANE

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 carton and on the 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 25 mg film-coated tablets contain

- Each tablet contains 25 mg exemestane which is the active substance.

- Your medicine also contains the following inactive ingredients: silica colloidal anhydrous, crospovidone, hypromellose, mannitol, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and polysorbate 80. The tablet coating contains Opadry white OYS 9622 (which consists of: hypromellose, propylene glycol and titanium dioxide (E171)).

What Exemestane 25 mg film-coated tablets look like and contents of the pack
White, round, biconvex, film-coated tablets embossed with an 'E' on one side.

Your medicine is supplied in blister packs containing 15, 20, 30, 90, 100 or 120 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Glenmark Pharmaceuticals Europe Ltd, Laxmi House, 2B Draycott Avenue, Kenton, Middlesex, HA3 0BU UK

Manufacturer:
Genepharm S.A., 18 Km Marathon Avenue, 15351 Pallini, Greece

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