

Package leaflet: Information for the patient

Exemestane 25mg 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 25mg film-coated tablets* are and what they are used for
2. What you need to know before you take *Exemestane 25mg film-coated tablets*
3. How to take *Exemestane 25mg film-coated tablets*
4. Possible side effects
5. How to store *Exemestane 25mg film-coated tablets*
6. Contents of the pack and other information

1. What Exemestane 25 mg film-coated tablets are and what it is used for

Your medicine is called *Exemestane 25mg film-coated tablets*. *Exemestane 25mg film-coated tablets* belongs to a group of medicines known as aromatase inhibitors. These drugs interfere with an enzyme 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 25mg 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 25mg 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 25 mg film-coated tablets

Do not take Exemestane 25mg film-coated tablets:

- If you are allergic to exemestane or any of 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, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Exemestane 25 mg film-coated tablets

- Before treatment with Exemestane 25mg film-coated tablets, your doctor may want to take blood samples to make sure you have reached the menopause.
- if you have problems with your liver or kidneys.
- if you have a history of or are suffering from any condition which affects the strength of your bones (e.g. Osteoporosis). Your doctor may want to measure your bone density before and during the treatment of Exemestane 25mg film-coated tablets. This is because drugs of this class lower the levels of female hormones which help in bone growth. This may lead to a loss of the mineral content of bones, which might decrease their strength.
- if you know you have low levels of vitamin D (for example you are unable to spend time in natural sunlight). Your doctor may want to check your Vitamin D levels before treatment and, if needed, give you Vitamin D supplements.

Other medicines and Exemestane 25 mg film-coated tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Exemestane 25 mg film-coated tablets should not be given at the same time as hormone replacement therapy (HRT) or with any oestrogen-containing medicines (including combined oral contraceptive pills).

The following medicines should be used cautiously when taking Exemestane 25 mg film-coated tablets. Let your doctor know if you are taking medicines such as:

- rifampicin (an antibiotic),
- (anticonvulsants used to treat epilepsy, (carbamazepine or phenytoin)
- herbal remedy St Johns wort (*Hypericum perforatum*), or preparations containing it.

Pregnancy and breast-feeding

Do not take Exemestane 25 mg film-coated tablets if you are pregnant, likely to be pregnant or breastfeeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 25mg film-coated tablets, you should not attempt to drive or operate machinery.

Exemestane 25 mg film-coated tablets 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 25 mg film-coated tablets

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

Adults and the elderly

Exemestane 25mg film-coated tablets 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.

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

If you need to go to the hospital whilst taking Exemestane 25mg film-coated tablets, let the medical staff know what medication you are taking.

Use in children and adolescents

Exemestane 25mg film-coated tablets are not suitable for use in children and adolescents below 18 years.

If you take more Exemestane 25 mg film-coated 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 25 mg film-coated tablets tablets.

If you forget to take Exemestane 25 mg film-coated 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 25 mg film-coated tablets

Do not stop treatment without consulting your doctor. If you stop the treatment your symptoms might reappear.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In general, Exemestane 25 mg film-coated tablets are well tolerated and the following side effects observed in patients treated with Exemestane 25 mg film-coated tablets are mainly mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes).

If you experience the following, stop taking the tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger)

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

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath , wheezing or trouble breathing (anaphylaxis)

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

- Inflammation of the liver (hepatitis) may occur or blockage in the bile duct which may cause yellowing of the skin or eyes, feeling generally unwell, nausea, itching, right sided abdominal pain and loss of appetite.
- Rapid appearance of skin rash, red and swollen areas or patches of the skin studded with small fluid-filled blisters, skin inflammation, flaking or peeling of the skin over the body which may also be associated with fever.

The following side effects have also been reported

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

- Depression
- Difficulty sleeping
- Headache
- Hot flushes
- Dizziness
- Feeling sick, nausea
- Increased sweating
- Muscle and joint pain, including swelling, creaking, stiffness and pain of one or more joints)
- Tiredness
- A reduction in the number of white blood cells (leucopenia)
- Stomach pain
- Elevated liver enzymes
- Elevated level of haemoglobin breakdown in the blood
- Elevated level of a certain blood enzyme due to liver damage
- Pain

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

- Loss of appetite, weight loss
- Being sick (vomiting), constipation, indigestion, diarrhoea
- Skin rash, hives and itching,
- Hair loss
- Swollen hands and feet
- Pins and needles
 - A reduction in the number of platelets in the blood (thrombocytopenia)
- Muscle weakness

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

- Drowsiness

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

- Low level of certain white blood cells (lymphocytes) in the blood

If you have any blood tests done, it may be noticed that there are changes in your liver function (increase in liver enzymes and bilirubin). Changes in the amount of white blood cells (so-called leucocytes and lymphocytes) and platelets circulating in your blood may occur, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood). You may have increased bruising and bleeding than normal or more easily get infections (with symptoms e.g. sore throat, fever, severe chills).

In clinical studies the following side effects have been noted but it has not been established if these are related to the medicine itself:

- changes in vagina and womb, vaginal bleeding,
- changes in vision,
- blockage of blood vessel due to blood clotting, heart attack, increased blood pressure, heart failure,
- changes in or increased levels of cholesterol and other fats in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Exemestane 25 mg film-coated tablets

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

- This medicine does not require any special storage conditions.
- 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 to protect the environment.

6. Contents of the pack and other information

What Exemestane 25 mg film-coated tablets contain:

The active ingredient is Exemestane (as exemestane).

Each film-coated tablet contains 25 mg of Exemestane (as exemestane).

The other ingredients are:

Tablet Core: Silica, colloidal anhydrous, crospovidone, hypromellose 5cP, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate 80 and sodium starch glycolate (Type A).

Film-coating: hypromellose 5cP, macrogol, talc and titanium dioxide (E171).

What Exemestane 25 mg film-coated tablets look like and contents of the pack

Exemestane 25 mg film-coated tablets are white, round biconvex film-coated tablets

Exemestane 25 mg film-coated tablets are available in blister packs of 14, 15, 20, 30, 60, 90, 100 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

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