**PACKAGE LEAFLET:**
**INFORMATION FOR THE USER**

MORNINGSIDE HEALTHCARE

# Exemestane

PHARMACODE

**25 mg** film-coated tablets

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


## 1. What Exemestane is and what it is used for

Your medicine is called Exemestane. 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 hormone, oestrogen, especially in postmenopausal women. Reducing 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.
It 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

**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 Exemestane (Please see section 6),
- have **not** already been through 'the menopause', i.e. you are still having your monthly period,
- are pregnant, likely to be pregnant or breast-feeding

**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 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 Exemestane**
Tell your doctor 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 (anti-convulsants used to treat epilepsy),
- the herbal remedy St John's 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.

**Important information about Exemestane film-coated tablets**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Exemestane

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

**Adults and the elderly patients**
The usual dose is one 25 mg film-coated tablet daily. Exemestane film-coated tablets should be taken by mouth after a meal at approximately the same time each day.

**Use in children and adolescents**
Exemestane is not suitable for use in children and adolescents.

**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 film-coated tablets.

**If you forget to take Exemestane**
Do not take a double dose to make up for a forgotten dose.
If you forget to take your film-coated 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 film-coated 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 or pharmacist.

## 4. Possible side effects

Like all medicines, Exemestane 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
- 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**
- 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

**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

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 the Yellow Card Scheme at: 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 Exemestane after the expiry date which is stated on the carton after <EXP>.
The expiry date refers to the last day of that month.

This 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 contains**

The active substance is exemestane. Each film coated tablet contains 25 mg exemestane.
The other ingredients are:

*Tablet core:*
Mannitol, Copovidone, Crospovidone, Silicified Microcrystalline Cellulose, Sodium Starch Glycolate (Type A), Magnesium Stearate.

*Film coating:*
Hypromellose, Macrogol 400,Titanium Dioxide.

**What Exemestane looks like and contents of the pack**
White to off-white, round compound cup tablet, with “25” on one side and plain on the reverse.

**Exemestane** is available in blister packs of:
10, 14, 20, 30, 60, 90 and 100 (Blisters of 10 or 14) film-coated tablets.
Not all pack sizes may be marketed.

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