

## Package Leaflet: information for the patient

# Exemestane 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 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 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

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

### Do not take Exemestane

- If you are **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. if you are still having your monthly periods.
- If you are **pregnant, likely to be pregnant or breast-feeding**.

### Warnings and precautions

Talk to your doctor or pharmacist 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 a vitamin D supplement if your levels are below normal.
- If you have problems with your **liver or kidneys**.
- 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 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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** (medicines used to treat fits),
- the herbal remedy **St Johns Wort** (*Hypericum perforatum*), which is used to treat depression and general inflammation, or preparations containing it.

### Pregnancy and breast-feeding

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.

### Do not take Exemestane if you are pregnant or breast-feeding.

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 glucose

If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.

### 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

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

### Adults and the elderly

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

The recommended dose is **one 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 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 for advice immediately. Show them the pack of exemestane.

### 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 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 exemestane 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, this medicine can cause side effects, although not everybody gets them.

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).

### Contact your doctor immediately to seek urgent medical advice if you think you experience any of the following serious side effects:

**Very common** (may affect more than 1 in 10 people):

- A reduction in the number of white blood cells.

**Common** (may affect up to 1 in 10 people):

- A reduction in the number of platelets in the blood.

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

- Allergic reaction (symptoms include sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, fever, rash or itching (especially affecting the whole body).

**Rare** (may affect up to 1 in 1000 people):

- Inflammation of the liver (hepatitis).
- 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.

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

- Low level of certain white blood cells (lymphocytes).

Changes in the amount of certain blood cells (lymphocytes) and platelets circulating in your blood may occur, especially in patients with a pre-existing reduction of lymphocytes in the blood (lymphopenia).

Other side effects:

**Very common** (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 inflammation of the joints, back pain, and joint stiffness).
- Tiredness.
- Abdominal pain.
- Elevated level of liver enzymes.
- Elevated level of a haemoglobin breakdown product 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.
- Being sick (vomiting), 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.
- 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.

#### 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](http://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 to 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.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton 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 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 mannitol (E421), hypromellose, crospovidone, polysorbate 80, microcrystalline cellulose, sodium starch glycolate type A, magnesium stearate, colloidal anhydrous silica.
- The ingredients in the tablet coating are carmellose sodium (E466), maltodextrin, glucose monohydrate, titanium dioxide (E171), stearic acid (E570), iron oxide yellow (E172).

### What Exemestane looks like and contents of the pack

Exemestane is a yellow film-coated biconvex round tablet, debossed with 'E9MT' on one side and '25' on the other side.

Exemestane tablets are available in blister packs of 30, 90, 100 and 120 tablets; unit-dose of 30 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:  
Zentiva Pharma UK Limited,  
12 New Fetter Lane, London,  
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Manufacturers:  
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