

## 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 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 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 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.
- Before taking Exemestane, tell your doctor 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. 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. You may have to undergo tests to measure your bone density before and during treatment. Your doctor can give you medications or Vitamin D supplements to prevent or treat the bone loss.

### **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 (anti-convulsants used to treat epilepsy),
- the herbal remedy St John's wort (*Hypericum perforatum*), or preparations containing it.

### **Pregnancy, breast-feeding and fertility**

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**

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 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 usual dose is one 25 mg film-coated 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 recommended 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

**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, 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 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
- Skin rash, hives and itchiness
- Hair loss
- 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 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.

### **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 national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store exemestane**

This medicine does not require any special storage conditions.  
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.

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:

30 tablets (Blisters of 10) film-coated tablets.

100 tablets (Blisters of 100) film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Rivopharm UK Ltd.  
100 Bishopsgate  
London  
EC2N 4AG  
United Kingdom

#### **Manufacturer**

EirGen Pharma Ltd.  
Westside Business Park, Old Kilmeaden Road, Waterford  
Ireland

**This medicinal product is authorised in the Member States of the EEA under the following names:**

*UK:* Exemestane 25mg Film-coated tablets

*ES:* Exemestano Aurovitas Spain 25 mg comprimidos recubiertos con película EFG

**This leaflet was last revised in 07/2023**