

## Package leaflet: Information for the patient

### Exemestaan 25 mg Teva, filmomhulde tabletten

exemestaan

**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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What <Product Name> is and what it is used for
2. What you need to know before you take <Product Name>
3. How to take <Product Name>
4. Possible side effects
5. How to store <Product Name>
6. Contents of the pack and other information

#### 1. What <Product Name> is and what it is used for

Your medicine is called <Product Name>. <Product Name> 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.

<Product Name> 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.

<Product Name> 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 <Product Name>

##### Do not take <Product Name>

- 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, pharmacist or nurse before taking <Product name>

- Before treatment with <Product Name>, 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 <Product Name>, 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 <Product Name>. 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.

### **Children and adolescents**

<Product Name> is not recommended for use in children and adolescents.

### **Other medicines and <Product Name>**

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

<Product Name> should not be given at the same time as hormone replacement therapy (HRT).

The following medicines should be used cautiously when taking <Product Name>. 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 John's Wort (*Hypericum perforatum*), or preparations containing it.

### **Pregnancy and breast-feeding**

Do not take <Product Name> 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 <Product Name>, you should not attempt to drive or operate machinery.

### **<Product name> contains sodium**

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

## **3. How to take <Product Name>**

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

### **Adults and elderly patients**

<Product Name> tablets should be taken by mouth after a meal at approximately the same time each day.

Your doctor will tell you how to take <Product Name> and for how long.

The recommended dose is one 25 mg tablet daily.

If you need to go to the hospital whilst taking <Product Name>, let the medical staff know what medication you are taking.

### **If you take more <Product Name> 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 <Product Name> tablets.

### **If you forget to take <Product Name>**

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 <Product Name>**

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 <Product Name> is well tolerated and the following side effects observed in patients treated with <Product Name> 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 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 (blood cells which cause clotting) 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 national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store <Product Name>**

- 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 blister after EXP. The expiry date refers to the last day of that month.
- This medicine 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 <Product Name> 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 (containing Microcrystalline cellulose & Silica, colloidal anhydrous), Sodium starch glycolate (Type A), Magnesium stearate

Film coating

Hypromellose, Macrogol 400, Titanium dioxide

**What <Product Name> looks like and contents of the pack**

<Product Name> is a white to off-white, round compound cup tablet of 6 mm diameter, with “25” on one side and plain on the reverse.

<Product Name> is available in blister packs of 10, 14, 20, 30, 50x1, 60, 90, 100 (Blister packs of 10 or 14 or 30) film-coated tablets.

Not all pack sizes may be marketed.

**Houder van de vergunning voor het in de handel brengen en fabrikant**

*Houder van de vergunning voor het in de handel brengen*

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**In het register ingeschreven onder**  
RVG 104488

**Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

Frankrijk: Exemestane Teva 25 mg, comprimé pelliculé  
Griekenland: Exemestane / Teva 25mg Επικαλυμένα με λεπτό υμένιο δισκία  
Italië: Exemestane Teva 25mg compresse rivestite  
Nederland: Exemestaan Teva 25 mg, filmomhulde tabletten  
Spanje: Exesmestano Teva-ratiopharm 25 mg comprimidos recubiertos EFG

**Deze bijsluiter is voor het laatst goedgekeurd in november 2025.**