

Exemestane 25 mg film-coated tablets

exemestane

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Exemestane 25 mg is and what it is used for
2. Before you take Exemestane 25 mg
3. How to take Exemestane 25 mg
4. Possible side effects
5. How to store Exemestane 25 mg
6. Further information

1. WHAT EXEMESTANE 25 MG 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 for treating

- hormone dependent early breast cancer in postmenopausal women after they have completed 2-3 years of treatment with the medicine tamoxifen
- hormone dependent advanced breast cancer in postmenopausal women when a different hormonal drug treatment has not worked well enough.

2. BEFORE YOU TAKE EXEMESTANE 25 MG

Do not take Exemestane 25 mg

- if you are or have previously been **allergic (hypersensitive) to exemestane or to any of the other ingredients** of Exemestane 25 mg (see section 6, 'What Exemestane 25 mg contains' for a full list of ingredients).
- if you have **not yet gone through the menopause** i.e. if you still have periods.
- if you are **pregnant or likely to get pregnant**.
- if you are **breast-feeding**.

Take special care with Exemestane 25 mg

- if you have problems with your **liver or kidneys**, you will need to inform your doctor about it.
- 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.

Before treatment with Exemestane 25 mg your doctor may want to take blood samples to make sure you have reached the menopause.

Taking other medicines

Other medicines may be affected by exemestane. They, in turn, may affect how well exemestane works.

Exemestane 25 mg **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.

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Exemestane 25 mg with food and drink

Exemestane 25 mg should be taken after a meal.

Pregnancy and breast-feeding

Exemestane 25 mg **should not be taken during pregnancy and breast-feeding** as it may harm your baby.

Contact your doctor immediately if you think you are pregnant.

Discuss contraception with your doctor if there is any possibility that you may become pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

Important information about some of the ingredients of Exemestane

Exemestane tablets contain glucose monohydrate. If you have previously been told that you have **intolerance to some sugars**, contact your doctor before taking this medicine.

3. HOW TO TAKE EXEMESTANE 25 MG

Always take Exemestane 25 mg exactly as your doctor has told you. You should 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 25 mg tablet daily**.

If you need to go to the hospital whilst taking exemestane, let the medical staff know what medication you are taking.

Children

Exemestane 25 mg is not suitable for use in children.

If you take more Exemestane 25 mg than you should

If you have taken too much Exemestane 25 mg, or if someone else accidentally took your tablets, contact your doctor, pharmacy or hospital for advice immediately.

Show them the pack of Exemestane 25 mg.

If you forget to take Exemestane 25 mg

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 25 mg

Do not stop taking Exemestane 25 mg even if you are feeling well, unless your doctor tells you. Your doctor will advise you on how long you should continue to take your tablets.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, exemestane can cause side effects, although not everybody gets them.

Most of the side effects are mild to moderate. Some of these side effects, such as hot flushes may be due to the lack of oestrogens in your body.

Inflammation of the liver (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 immediately if you think you have any of these symptoms.

Very common side effects (affects more than 1 user in 10)

- Difficulty sleeping
- Headache
- Hot flushes
- Feeling sick
- Increased sweating
- Muscle and joint pain (including inflammation of the joints, back pain, and joint stiffness)
- Tiredness

Common side effects (affects 1 to 10 users in 100)

- Loss of appetite
- Depression
- Dizziness
- a combination of pins and needles, numbness and pain affecting all of the hand except the little finger (carpal tunnel syndrome)
- Stomach ache, being sick (vomiting), constipation, indigestion, diarrhea
- Skin rash, hair loss
- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Pain, swollen hands and feet

Uncommon side effects (affects 1 to 10 users in 1,000)

- Drowsiness
- Muscle weakness

If you have any blood tests done, it may be noticed that there are changes in your liver function. 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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EXEMESTANE 25 MG

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Exemestane 25 mg after the expiry date which is stated on the blister and carton after EXP. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Exemestane 25 mg 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 25 mg looks like and contents of the pack

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

Exemestane 25 mg tablets are available in blister packs of 30, 90 and 100 tablets; unit-dose of 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Consilient Health Limited, 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland

Manufacturers:

Synthon BV, Microweg 22, 6545 CM Nijmegen, The Netherlands.

Synthon Hispania S.L. Castelló 1, Polígono Las Salinas, 08830 Sant Boi de Llobregat, Spain.

This leaflet was last revised in 07/2019.