

Package leaflet: Information for the user

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

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

Exemestane Actavis 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.

Exemestane Actavis 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 Actavis 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 Actavis

Do not take Exemestane Actavis

- if you are or have previously been allergic to exemestane (the active ingredient in Exemestane Actavis) 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 Exemestane Actavis.

- Before treatment with Exemestane Actavis, 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 Actavis, 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 Exemestane Actavis. 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 Actavis

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 Actavis should not be given at the same time as hormone replacement therapy (HRT).

The following medicines should be used cautiously when taking Exemestane Actavis. 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 Exemestane Actavis 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 Actavis, you should not attempt to drive or operate machinery.

Exemestane Actavis 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 Exemestane Actavis

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

Adults and elderly patients

Exemestane Actavis tablets should be taken by mouth after a meal at approximately the same time each day. Your doctor will tell you how to take Exemestane Actavis and for how long. The recommended dose is one 25 mg tablet daily.

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

Use in children

Exemestane Actavis is not suitable for use in children.

If you take more Exemestane Actavis 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 Actavis tablets.

If you forget to take Exemestane Actavis

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 Exemestane Actavis

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, Exemestane Actavis is well tolerated and the following side effects observed in patients treated with Exemestane Actavis 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 (nausea)
- 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 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 HPR
Pharmacovigilance Website: www.hpra.ie

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

5. How to store Exemestane Actavis

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

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.

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 Actavis contains

- The active substance is exemestane. Each film-coated tablet contains 25 mg exemestane.
- The other ingredients are: core: povidone K30; maize starch (bleached), starch, pregelatinized (partially), sodium starch glycolate type A, cellulose microcrystalline type 101, talc, silica colloidal anhydrous, magnesium stearate and polysorbate 80; film-coating: polyvinyl alcohol partially hydrolyzed, talc, macrogol 3350 and titanium dioxide (E171).

What Exemestane Actavis looks like and contents of the pack

Exemestane Actavis 25 mg film-coated tablet is white, round, lenticular, with uniform appearance and intact edges.

Pack sizes:

Blister packs: 10, 30, 40, 60, 84, 90 and 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

S.C. Sindan-Pharma S.R.L.,
11 Ion Mihalache Blvd.
011171 Bucharest,
Romania

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

Ireland: Exemestane Actavis 25 mg Film-coated Tablets

Iceland: Exemestan Actavis

Sweden: Exemestan Actavis

This leaflet was last revised in February 2020.