



ΕΤΑΙΡΕΙΑ: GENEPHARM

ΠΡΟΪΟΝ: Exemestane/Genepharm leaflet

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ΔΙΑΣΤΑΣΕΙΣ: 140 x 200 mm

ΧΡΩΜΑΤΑ: Black

ΕΚΔΟΣΗ: 1η

ΗΜΕΡΟΜΗΝΙΑ: 30/8/2012

ΠΑΡΑΤΗΡΗΣΕΙΣ: χαρτί 60gr

Διπλωμένη 140 x 30 mm



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#### PACKAGE LEAFLET: INFORMATION FOR THE USER

##### Exemestane/Genepharm 25 mg film-coated tablets

#### 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/Genepharm tablets are and what it are used for
2. Before you take Exemestane/Genepharm tablets
3. How to take Exemestane/Genepharm tablets
4. Possible side effects
5. How to store Exemestane/Genepharm tablets
6. Further information

#### 1. WHAT EXEMESTANE TABLETS ARE AND WHAT IT ARE USED FOR

Exemestane/Genepharm tablets belong 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/Genepharm tablets are 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/Genepharm tablets are also used to treat hormone dependent advanced breast cancer in postmenopausal women when a different hormonal drug treatment has not worked well enough.

#### 2. BEFORE YOU TAKE Exemestane/Genepharm TABLETS

##### Do not take Exemestane/Genepharm tablets:

- If you are or have previously been allergic (hypersensitive) to exemestane or any of the other ingredients. See section 6 ('Further information') for full list of other ingredients;
- 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 breastfeeding.

##### Take special care with Exemestane/Genepharm tablets:

- Before taking Exemestane/Genepharm tablets, your doctor may want to take blood samples to make sure you have reached the menopause;
- Before taking Exemestane/Genepharm tablets, 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 with Exemestane/Genepharm tablets. 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.

#### Using other medicines

Please tell your doctor if you are taking or have recently taken 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/Genepharm tablets. 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. Johns Wort (Hypericum perforatum), or preparations containing it.

#### Taking Exemestane/Genepharm tablets with food and drink

Exemestane/Genepharm tablets should be taken after a meal at approximately the same time each day.

#### Pregnancy and breast-feeding

Do not take Exemestane/Genepharm if you are pregnant or breastfeeding.

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/Genepharm tablets, you should not attempt to drive or operate machinery.

#### 3. HOW TO TAKE EXEMESTANE TABLETS

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



Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

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

#### This medicine is not suitable for use in children.

#### If you take more Exemestane/Genepharm tablets than you should:

If you accidentally take too many tablets, contact your doctor immediately.

#### If you forget to take Exemestane/Genepharm tablets:

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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/Genepharm tablets can cause side effects, although not everybody gets them. In general, your medicine is well tolerated and the following side effects have been observed in patients treated with Exemestane/Genepharm tablets and 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 side effects, (affecting more than 1 person in 10):

- Difficulty sleeping
- Headache
- Hot flushes
- Feeling sick
- Increased sweating
- Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- Tiredness

#### Common side effects, (affecting between 1 to 10 people in 100):

- Loss of appetite
- Depression
- Dizziness, carpal tunnel syndrome (a combinations of pins and needles, numbness and pain affecting all of the hand except the little finger)
- Stomach ache, vomiting (being sick), constipation, indigestion, diarrhoea
- 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, (affecting between 1 to 10 people in 1000):

- 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 lymphopenia (reduced lymphocytes in the blood).

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/Genepharm TABLETS

Keep out of the reach and sight of children.

Do not use Exemestane/Genepharm tablets after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

Your medicine doesn't require any special storage conditions.

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/Genepharm tablets contain

- Each tablet contains 25 mg exemestane which is the active substance.

• Your medicine also contains the following inactive ingredients: silica colloidal anhydrous, crospovidone, hypromellose, mannitol, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and polysorbate 80. The tablet coating contains Opadry white OYS 9622 (which consists of: hypromellose, propylene glycol and titanium dioxide (E171)).

##### What Exemestane/Genepharm tablets look like and contents of the pack

White, round, biconvex film-coated tablets, embossed with the letter E on one side.

Your medicine is supplied in blister packs containing 30 film-coated tablets.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder:

Genepharm S.A., 18 Km Marathon Avenue, 15351 Pallini, Greece

##### Manufacturer:

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