

PACKAGE LEAFLET: INFORMATION FOR THE USER

Exmachan 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 your pharmacist.

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1. What Exmachan is and what it is used for

Your medicine is called Exmachan. Exmachan 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.

Exmachan 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.

Exmachan 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. Before you take Exmachan

Do not take Exmachan

- if you are or have previously been allergic (hypersensitive) to exemestane (the active ingredient in Exmachan) or any of the other ingredients of Exmachan. See section 6 ("What Exmachan contains") 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 Exmachan

- Before treatment with Exmachan, your doctor may want to take blood samples to make sure you have reached the menopause.
- Before taking Exmachan, 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 Exmachan. 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.

Taking other medicines

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

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

The following medicines should be used cautiously when taking Exmachan. Let your doctor know if you are taking medicines such as:

- rifampicin (an antibiotic),
- carbamazepine or phenytoin (anticonvulsants used to treat epilepsy),
- herbal remedy St Johns Wort (*Hypericum perforatum*), or preparations containing it.

Pregnancy and breast-feeding

Do not take Exmachan 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.

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

Driving and using machines

If you feel drowsy, dizzy or weak whilst taking Exmachan, you should not attempt to drive or operate machinery.

3. How to take Exmachan**Adults and the elderly**

Exmachan tablets should be taken by mouth after a meal at approximately the same time each day. Your doctor will tell you how to take Exmachan and for how long. The recommended dose is one 25 mg 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 Exmachan, let the medical staff know what medication you are taking.

Children

Exmachan is not suitable for use in children.

If you take more Exmachan 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 Exmachan tablets.

If you forget to take Exmachan

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

4. Possible side effects

Like all medicines, Exmachan can cause side effects, although not everybody gets them. In general, Exmachan is well tolerated and the following side effects observed in patients treated with Exmachan 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

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 promptly if you think you have any of these symptoms.

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 side effects get serious or if you notice any side effect not listed on this leaflet, please tell your doctor or your pharmacist as soon as possible.

5. How to store Exmachan**Keep out of the reach and sight of children.**

- This medicine does not require any special storage conditions.
- Keep you tablets in the original pack.
Do not use Exmachan after expiry date which is stated on the outer carton and the blister after EXP. The expiry date refers to the last day of the 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 Exmachan contains:**

The active ingredient is exemestane.

Each film-coated tablet contains 25 mg of exemestane.

The other ingredients are:

Tablet Core: Silica, colloidal anhydrous, Crospovidone, Hypromellose 5cP, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Polysorbate 80 and Sodium Starch Glycolate (Type A).
Film-coating: Hypromellose 5cP, Macrogol, Talc and Titanium Dioxide (E171).

What Exmachan looks like and contents of the pack

Exmachan 25 mg Film-coated Tablets is white, round biconvex film-coated tablets
Exmachan 25 mg Film-coated Tablets is available in blister packs of 15, 20, 30, 90 100 120 tablets.

Not all pack sizes will be marketed.

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Approved by: _____

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