

Exetas 25 mg Tablets

Exemestane Tablets (25 mg)

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What Exetas 25mg Tablets is used for

Exetas 25mg Tablets is indicated for the adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer, following 2 – 3 years of initial adjuvant tamoxifen therapy.

Exetas is indicated for the treatment of advanced breast cancer in women with natural or induced postmenopausal status whose disease has progressed following anti-oestrogen therapy. Efficacy has not been demonstrated in patients with oestrogen receptor negative status.

How Exetas works

Exetas 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, estrogens, especially in postmenopausal women. Reduction in oestrogen levels in the body is a way of treating hormone dependent breast cancer.

Before you use Exetas

-When you must not take it

- You are allergic to exemestane or any of the other ingredients of Exetas tablets.

- You still have periods, i.e. if you have not yet gone through the menopause.
- You are pregnant
- You are breast-feeding

-Before you start to take it

- Before treatment with Exetas, your doctor may want to take blood samples to make sure you have reached the menopause.
- Tell your doctor if you have problems with your liver or kidneys
- Tell your doctor if you have a history of osteoporosis (thinning or wasting of bones) or bone fractures.

-Taking other medicines

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

Children and adolescents (below 18 years)

Exetas is not to be used in children or adolescents.

Older people (age 65 years and over)

Exetas tablet can be used by people aged 65 years and over at the same dose as for other adults.

Taking Exetas Tablets with food and drink:

- Taking food and drink has no influence on your treatment with Exetas Tablets.

Pregnancy and breast-feeding:

- Exetas tablets are not recommended during pregnancy and breast-feeding.

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

How to use Exetas

-How much to use

The usual dose of Exetas tablets is one tablet once daily after a meal.

-When to take it

Always take Exetas tablets exactly as your doctor has told you.

Taking Exetas tablets at the same time each day will help you remember when to take your tablet.

-How long to take it

Continue taking Exetas tablets every day for as long as your doctor tells you. You may need to take them for months or even years. If you have any questions about how long to keep taking Exetas tablets, talk to your doctor.

-If you forget to take it

Do not take a double dose to make up for the forgotten dose, take it as soon as you remember. Then take your next dose as usual.

-If you take too much (Overdose)

If you accidentally take too many Exetas, than you have been told to take, or if someone else accidentally takes your medicine, contact your doctor or hospital for advice immediately. Take your medicine with you.

While you are using Exetas Tablets

-Things you must do

If you become pregnant while taking Exetas Tablets, tell your doctor immediately.

You should not take this medicine while you are pregnant.

Follow your doctor's instructions carefully.

If you do not follow your doctor's instructions, your treatment may not help or you may have unwanted side effects. Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want you to have blood tests from time to time to check on your progress and detect any unwanted side effects. Your doctor may also decide to monitor your bone health as this medicine may cause thinning or wasting of your bones (osteoporosis).

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Exetas Tablets.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Exetas Tablets.

-Things you must not do

Do not use Exetas Tablets to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their symptoms seem to be similar to yours.

-Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Exetas Tablets until you know how it affects you.

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side Effects:

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

Most of the side effects are mild to moderate. and will generally disappear after a few days to few weeks of treatment. However, if they are severe or last for more than a few days, tell your doctor.

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):

- Depression

- difficulty sleeping
- headache
- Dizziness
- hot flushes
- stomach ache
- Nausea
- Hepatic enzyme increased
- blood bilirubin increased
- K Phosphatase increased
- 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
- 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, diarrhea
- skin rash, hair loss
- thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- swollen hands and feet

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers -> Reporting Side Effects to Medicines

Storage and Disposal of Exetas

-Storage

Keep out of the reach and sight of children.

Store below 30 °C

-Disposal

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.

Product Description:

-What it looks like

Exetas 25 mg Tablets are packed in Opaque White PVC/PVdC-Alu blister. Each printed carton contain 3 such blisters.

-Ingredients

-Active ingredients(s)

Exemestane 25mg..

-Inactive ingredients:

Mannitol, Cellulose Microcrystalline, Crospovidone, Sodium starch Glycolate (Type A), Hypromellose E5, Polysorbate 80, Colloidal Anhydrous Silica, Magnesium stearate,

Tablet Coating:

Hypromellose 6cp (E464) Macrogol (400)

Titanium dioxide (E171)

-MAL number:

MAL 17085041AZ

Manufacturer:

Intas Pharmaceuticals Ltd. Matoda, 382 210,
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INDIA

Product registration Holder:

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