

osteoporosis should have treatment baseline bone mineral health assessment based on current clinical guidelines and practice. Patients with advanced disease should have their bone mineral density assessed on a case-by-case basis. Although adequate data to show the effects of therapy in the treatment of the bone mineral density loss caused by Exemestane are not available, patients treated with Exemestane should be carefully monitored and treatment for, or prophylaxis of, osteoporosis should be initiated in at risk patients.

- Routine assessment of 25 hydroxy vitamin D levels prior to the start of aromatase inhibitor treatment should be considered, due to the high prevalence of severe deficiency in women with early breast cancer. Women with Vitamin D deficiency should receive supplementation with Vitamin D.

Pregnancy

Pregnancy Category X

It can cause fetal harm when administered to a pregnant woman. Studies on animals have shown reproductive toxicity. Exemestane is therefore contraindicated in pregnant women.

Breast-feeding

It is not known whether exemestane is excreted into human milk. Exemestane should not be administered to lactating woman.

Women of perimenopausal status or child-bearing potential

The physician needs to discuss the necessity of adequate contraception with women who have the potential to become pregnant including women who are perimenopausal or who have recently become postmenopausal, until their postmenopausal status is fully established

SIDE EFFECTS

Blood and lymphatic system disorders:

Very common	Leucopenia(**)
Common	Thrombocytopenia(**)
Not known	Lymphocyte count decreased(**)

Immune system disorders:

Uncommon	Hypersensitivity
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Metabolism and nutrition disorders:

Common	Anorexia
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Psychiatric disorders:

Very common	Depression, insomnia
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Nervous system disorders:

Very common	Headache, dizziness
Common	Carpal tunnel syndrome, paraesthesia
Rare	Somnolence

Vascular disorders:

Very common	Hot flushes
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Gastrointestinal disorders:

Very common	Abdominal pain, nausea
Common	Vomiting, diarrhea, constipation, dyspepsia

Hepatobiliary disorders:

Very common	Hepatic enzyme increased, blood bilirubin increased, blood alkaline phosphatase increased
Rare	Hepatitis(+), cholestatic hepatitis(+)

Skin and subcutaneous tissue disorders:

Very common	Increased sweating
Common	Alopecia, rash, urticaria, pruritus
Rare	Acute generalised exanthematous Pustulosis(+)

Musculoskeletal and bone disorders:

Very common	Joint and musculoskeletal pain (*)
Common	Fracture, osteoporosis

General disorders and administration site conditions:

Very common	Pain, fatigue
Common	Oedema peripheral, asthenia

(*) Includes: arthralgia, and less frequently pain in extremity, osteoarthritis, back pain, arthritis, myalgia and joint stiffness.

(**) In patients with advanced breast cancer thrombocytopenia and leucopenia have been rarely reported. An occasional decrease in lymphocytes has been observed in approximately 20% of patients receiving Exemestane, particularly in patients with pre-existing lymphopenia; however, mean lymphocyte values in these patients did not change significantly over

time and no corresponding increase in viral infections was observed. These effects have not been observed in patients treated in early breast cancer studies.

DRUG INTERACTIONS

- In vitro evidence showed that the drug is metabolised through cytochrome P450 CYP3A4 and aldoketo reductase does not inhibit any of the major CYP isoenzymes. In a clinical pharmacokinetic study, the specific inhibition of CYP3A4 by ketoconazole showed no significant effects on the pharmacokinetics of exemestane.
- In an interaction study with rifampicin, a potent CYP450 inducer, at a dose of 600 mg daily and a single dose of exemestane 25 mg, the AUC of exemestane was reduced by 54% and Cmax by 41%. Since the clinical relevance of this interaction has not been evaluated, the co-administration of drugs, such as rifampicin, anticonvulsants (e.g., phenytoin and carbamazepine) and herbal preparations containing hypericum perforatum (St John's Wort) known to induce CYP3A4 may reduce the efficacy of Exemestane.
- Exemestane should be used cautiously with drugs that are metabolised via CYP3A4 and have a narrow therapeutic window. There is no clinical experience of the concomitant use of Exemestane with other anticancer drugs.
- Exemestane should not be co-administered with estrogen containing medicines as these would negate its pharmacological action.

CONTRAINDICATIONS

- Exemestane tablets are contraindicated in patients with a known hypersensitivity to the active substance or to any of the excipients.
- It is also contraindicated in pre-menopausal women and in pregnant or lactating women.

STORAGE & INSTRUCTIONS:

Store between 15-30°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered oncologist or on demand from cancer hospital and institution only.

HOW SUPPLIED

Xemest Tablet 25mg

30's film coated tablets.

خوراک و طریقہ استعمال:

سرطان کے ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند اونکولوجسٹ یا کینسر ہسپتال کے نسخے پر فروخت کریں۔

Manufactured by:

**PHARMASOL
PRIVATE LIMITED**

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Lahore, Pakistan.