

Femzole®

Letrozole
Tablet

Description

Letrozole is a potent and highly specific nonsteroidal aromatase inhibitor. It inhibits the aromatase enzyme by competitively binding to the haem of the cytochrome P450 subunit of the enzyme, resulting in a reduction of estrogen biosynthesis in all tissues. Letrozole exerts its antitumor effect by depriving estrogen dependent breast cancer cells of their growth stimulus. In postmenopausal women, estrogens are derived mainly from the action of the aromatase enzyme, which converts adrenal androgens, primarily androstenedione and testosterone to oestrone (E1) and oestradiol (E2). The suppression of estrogen biosynthesis in the peripheral tissues and the malignant tissues can be achieved by specifically inhibiting the aromatase enzyme.

Indications

Letrozole is indicated for the treatment of advanced breast cancer in postmenopausal women.

Dosage and Administration

Adult and Elderly Patients

The recommended dose of Femzole® tablet is 2.5 mg once daily, without regard to meals. Treatment with Letrozole should continue until tumor progression is evident.

No dose adjustment is required for elderly patients. Patients treated with Letrozole do not require glucocorticoid or mineralocorticoid replacement therapy.

Children: Not recommended for use in children.

Patients with hepatic and/or renal impairment

No dosage adjustment is required for patients with mild to moderate hepatic impairment (child-Pugh grade A and B) or renal impairment (creatinine clearance ≥ 10 ml/min).

Contraindications

Femzole® is contraindicated in patients with known hypersensitivity to Letrozole or any of its excipients.

Drug Interactions

Coadministration of Letrozole & Tamoxifen 20 mg daily resulted in a reduction of Letrozole plasma levels of 38% on average.

A pharmacokinetic interaction study with Cimetidine showed no clinically significant effect on Letrozole pharmacokinetics.

An interaction study with Warfarin showed no clinically significant effect of Letrozole on Warfarin pharmacokinetics.

Use in Pregnancy and Lactation

Letrozole is contraindicated during pregnancy & Lactation.

Side Effects

CNS: Headache, Somnolence, Dizziness, Depression.

Dermatologic: Hot flushes, Rash, Pruritus

GI: Nausea, Vomiting, Constipation, Diarrhoea, Abdominal Pain, Anorexia, Dyspepsia.

Musculoskeletal: Arthralgia

Respiratory: Dyspnea, Cough

Miscellaneous: Fatigue, Chest Pain, Viral Infections, Hypertensions, Peripheral edema, Weight increase, Hypercholesterolaemia, Osteoporosis, Hair loss, Vaginal bleeding.

Storage

Keep in a cool and dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Femzole® Tablet: Box containing 5 tablets in 1x5's blister strips. Each film coated tablet contains Letrozole USP 2.5 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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