



# Endofree<sup>®</sup> Tablet

Letrozole 2.5 mg

## Presentation

Endofree<sup>®</sup>: Each tablet contains Letrozole BP 2.5 mg.

## Description

Letrozole is a nonsteroidal aromatase inhibitor. It exerts its antitumor effect by depriving estrogen-dependent breast cancer cell of their growth stimulus. Letrozole inhibits the aromatase enzyme by competitively binding to the heme of the cytochrome P450 subunit of the enzyme, resulting in a reduction of estrogen biosynthesis in all tissues.

## Indications and Uses

- Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.
- Extended adjuvant treatment of early breast cancer in postmenopausal women who have received 5 years of adjuvant tamoxifen therapy.
- First-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.
- Treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

## Dosage and Administration

The recommended dose is one 2.5 mg tablet administered once a day, regardless to meals. In patients with advanced disease, treatment with Letrozole should be continued until tumor progression is evident. Treatment should be discontinued at tumor relapse.

No dose adjustment is required for elderly patients. Patients treated with Endofree<sup>®</sup> tablet do not require glucocorticoid or mineralocorticoid replacement therapy.

### Renal Impairment

No dosage adjustment is required for patients with renal impairment if creatinine clearance is 10 ml/min.

### Hepatic Impairment

No dosage adjustment is recommended for patients with mild to moderate hepatic impairment. The dose of Endofree in patients with cirrhosis and severe hepatic dysfunction should be reduced by 50%. The recommended dose for such patients is 2.5 mg administered every other day.

## Side-effects

Letrozole is generally well tolerated. The observed adverse reactions are mild or moderate in nature including hot flashes, night sweats, weight increase, nausea, vaginal bleeding & irritation, endometrial proliferation disorders etc.

## Precautions

Since fatigue and dizziness have been observed with the use of Letrozole and somnolence was uncommonly reported, caution is advised when driving or using machinery.

## Pregnancy & Lactation

*During pregnancy:* Letrozole is contraindicated during pregnancy.

*During lactation:* Letrozole is contraindicated during lactation.

## Contraindications

Endofree Tablet is contraindicated in patients with known hypersensitivity to Letrozole or any of its excipients.

## Drug interactions

A pharmacokinetic interaction study with cimetidine & warfarin showed no clinically significant effect on Letrozole pharmacokinetics. In in-vitro experiments, Letrozole & diazepam showed no significant inhibition in the metabolism of each other. Coadministration of Letrozole and tamoxifen 20 mg daily resulted in a reduction of Letrozole plasma levels of 38% on average. Clinical experience in the second-line breast cancer pivotal trials indicates that the therapeutic effect of Letrozole therapy is not impaired if Letrozole is administered immediately after tamoxifen.

## Overdose


Isolated cases of overdosage with Letrozole have been reported. No specific treatment for overdosage is known; treatment should be symptomatic and supportive.

## Storage

- Store in a cool and dry place away from light.
- Keep out of reach of children.

## Commercial Pack

Endofree<sup>®</sup>: Each box contains 1 blister strip of 5 tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Dhamrai Unit, Dhaka, Bangladesh  
® Registered Trademark

V.N. 01  
ENT