# Lerozol®

Letrozole USP

**COMPOSITION:**
**Lerozol®** Tablet: Each film coated tablet contains Letrozole USP 2.5mg..

**PHARMACOLOGY:**
Letrozole is a nonsteroidal aromatase inhibitor. It exerts its antitumor effect by depriving estrogen-dependent breast cancer cells of their growth stimulus. It inhibits the conversion of androgens to estrogens. 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.

**INDICATION**:
- 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 metastalic breast cancer.
- Treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

**DOSAGE & ADMINISTRATION:**
The recommended dose is one 2.5 mg tablet administered once a day, regardless to meals. In patients with advanced disease, treatment with **Lerozol®** 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 **Lerozol®** 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 Lerozole 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. the effect of hepatic impairment of **Lerozol®** exposure in noncirrhotic cancer patients with elevated bilirubin levels has not been determined.

**CONTRAINDICATION:**
Letrozole is contraindicated in patients with known hypersensitivity to Letrozole or any of its excipients.

**PRECAUTION:**
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.

**DRUG INTERACTION:**
An interaction study with warfarin showed no clinically significant effect of letrozole on warfarin pharmacokinetics. In in-vitro experiments, Letrozole showed no significant inhibition in the metabolism of diazepam. Coadministration of Letrozole and tamoxifen 20 mg daily resulted in a reduction of letrozole plasma lebels 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.

**ADVERSE EFFECT:**
**Lerozol®** (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 Disorder etc.

**USE IN PREGNANCY AND LACTATION:**
*Nursing Mothers*
It is not known if Letrozole is exerted in human milk. Because many drugs are exerted in human milk, caution should be exercised when letrozole is administered to a nursing woman.
*Pediatric use*
The safety and effectiveness in pediatric patients have not been established.

**STORAGE CONDITION:**
Store in a cool and dry place protected from light and moisture.

**HOW SUPPLIED:**
**Lerozol®** Tablet; Box containing 2 x 5 tablets in blister pack.

*Manufactured by*
**SQUARE**
**PHARMACEUTICALS LTD.**
**BANGLADESH**