

Lenor[®]

Letrozole USP Film Coated Tablet

DESCRIPTION

Lenor[®] is a preparation Letrozole. Letrozole is a non-steroidal 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. The suppression of estrogen biosynthesis in peripheral tissues and the cancer tissue itself can therefore be achieved by specifically inhibiting the aromatase enzyme.

INDICATIONS AND USAGES

- 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 prior standard adjuvant tamoxifen therapy.
- First-line treatment in postmenopausal women with hormone receptor positive or unknown, locally advanced or metastatic breast cancer
- Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antiestrogens.

DOSAGE AND ADMINISTRATION

- **Adult & Elderly patients:** The recommended dose of **Lenor[®]** is 2.5 mg once daily. In the adjuvant and extended adjuvant setting, treatment with **Lenor[®]** should continue for 5 years or until tumour relapse occurs, whichever comes first. In patients with metastatic disease, treatment with **Lenor[®]** should continue until tumour progression is evident. No dose adjustment is required for elderly patients.
- **Children:** Not applicable.
- **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

required for patients with mild to moderate hepatic impairment. The dose of **Lenor[®]** in patients with cirrhosis and severe hepatic impairment should be reduced by 50%. The recommended dose for such patient is 2.5 mg administered every other day. The effect of hepatic impairment on **Lenor[®]** exposure in noncirrhotic women patients with elevated bilirubin level has not been determined.

CONTRAINDICATIONS

- Known hypersensitivity to the active substance.
- In women having a premenopausal endocrine status, during pregnancy & lactation

SIDE-EFFECTS

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

USE IN PREGNANCY & LACTATION

Contraindicated during pregnancy and lactation.

PHARMACEUTICAL PRECAUTION

Keep in a dry & cool place (below 30°C temp.), away from light. Keep out of reach of children.

PACKAGING

Lenor[®] Tablet : Box containing 1 strip of 10 tablets. Each film coated tablet contains Letrozole USP 2.5 mg.

SK+F

Manufactured for
ESKAYEF BANGLADESH LIMITED
By POPULAR PHARMACEUTICALS LTD.
GAZIPUR, BANGLADESH
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