

Letromina™ Tablets 2.5mg

GENERIC NAME

Letrozole tablet 2.5mg

CHEMICAL NAME

4,4'-(1H-1,2,4-Triazol-1-ylmethylene)dibenzonitrile

MOLECULAR STRUCTURE

C₁₇H₁₁N₅

MOLECULAR WEIGHT

285.31

DOSAGE FORM: Each Film coated tablet contains Letrozole 2.5mg Tablet.

CATEGORY

Anticancer Drugs, Aromatase inhibitors

PHARMACOLOGICAL CLASSIFICATION

Letromina™ is an oral nonsteroidal aromatase inhibitor for adjuvant treatment of hormonally responsive breast cancer. Estrogens are produced by the conversion of androgens through the activity of the aromatase enzyme. Letrozole competitively inhibits the aromatase enzyme system by binding to the haem group of aromatase, cytochrome P450 enzyme, which catalyzes conversion of androgens to estrogens, leading to inhibition of the enzyme and significant reduction in plasma estrogen levels

PHARMACOKINETICS:

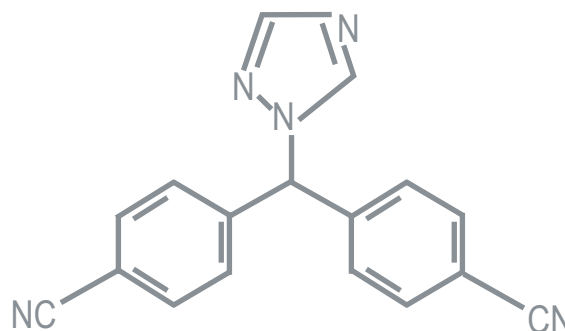
After oral administration, letrozole is readily absorbed from the gastro-intestinal tract with absolute bioavailability 99.9%. Food slightly decreases the rate of absorption, but the extent of absorption remains unchanged. The minor effect of the absorption rate is not considered to be of clinical relevance and therefore Letrozole may be taken after, with or before food.

Letromina™ is highly bound approximately 60% to Plasma protein, mainly to albumin (55%). The concentration of Letrozole in erythrocytes is approximately 80% in plasma.

Letromina™ is metabolised to a pharmacologically inactive carbinol metabolite(4,4'-methanol-bisbenzonitrile), The cytochrome P450 isoenzymes 3A4 and 2A6 were found to be capable of converting Letrozole to this metabolite in vitro but their individual contributions to Letrozole metabolism in vivo has not been established. The apparent terminal elimination half-life in plasma is around 2 days. After daily administration of 2.5 mg of Letromina™, steady-state levels are reached within 2 to 6 weeks. The apparent terminal elimination half-life in plasma is around 2 days. After daily administration of 2.5 mg of Letrozole, steady-state levels are reached within 2 to 6 weeks.



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INDICATIONS

Letromina™ is indicated for the following conditions :

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

DOSAGE & ROUTE OF ADMINISTRATION - Oral Administration

The recommended dose of Letrozole is 2.5 mg once daily. Treatment with Letrozole should continue as long as tumour response is seen. The drug should be discontinued if tumour stops responding as judged by tumour progression. For elderly patients, no modification of the normal adult dosage regimen is necessary.

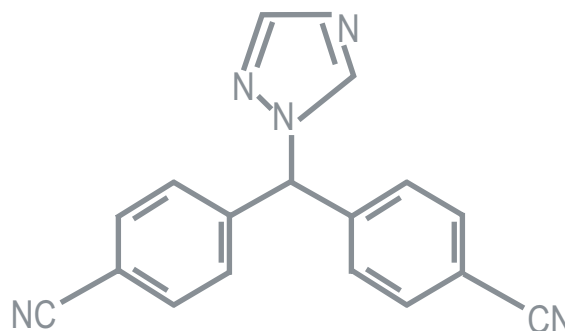
No dosage adjustment is required for patients with mild to moderate hepatic impairment or renal impairment.

ADVERSE EFFECTS

Hot flushes, musculoskeletal pain, arthralgia, headache, fatigue, nausea, vomiting, , hair thinning. dyspnoea, peripheral oedema, increased sweating coughing, constipation, vomiting, chest pain, , viral infection, Urinary tract infection, diarrhoea, rash, abdominal pain, dyspepsia and anorexia. Dizziness, weight increase and pruritus are less commonly seen. other less frequent 2% adverse effects are peripheral thromboembolic events like venous thrombosis, thrombophlebitis, portal vein thrombosis and pulmonary embolism, cardiovascular events included angina, myocardial infarction, coronary heart disease, cerebrovascular events included transient ischemic attacks, hemorrhagic strokes.



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CHEM

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MOLECUL

C17H11N5

MOLECULAR

285.31

DOSAGE FORM: E

Letrozole 2.5mg Tabl

DRUG INTERACTION

Clinical interaction studies with these drugs does not reveal known inhibitor of one of the *in vitro*.

Coadminstaration of Letrozole and plasma levels by 38% on average

CONTRAINDICATIONS

Letromina™ should not be used if you are taking any one of the tablet excipients. It is also contraindicated in pregnancy, lactation and in preparation for pregnancy.

WARNING & PRECAUTIONS

In breast cancer patients with renal impairment, but caution is recommended in patients with renal clearance.

Renal impairment

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OVERDOSAGE

There is no clinical experience of overdosage. There is no specific antidote to Letrozole.

Since Letrozole is not highly protein bound, dialysis may be helpful. Emesis may be induced if the patient is alert. In general, supportive care and frequent monitoring of vital signs is appropriate.

IDENTIFICATION

Letromina™ is a light yellow colored, Film coated round shaped tablet.

PRESENTATION

A strip of 2.5 mg strength of ten tablets in a blister. Such 3 blisters are packed in an individual carton with a leaflet.

STORAGE

Store in a cool dry place, protected from light. Keep out of reach of children.

MARKETED BY:

Alpha-Pharma Healthcare India Pvt. Ltd.
A-317, Sagar Tech Plaza
Andheri-Kurla Road
Sakinaka Junction, Andheri (E)
Mumbai-400072, India

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1st of November 2008.



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