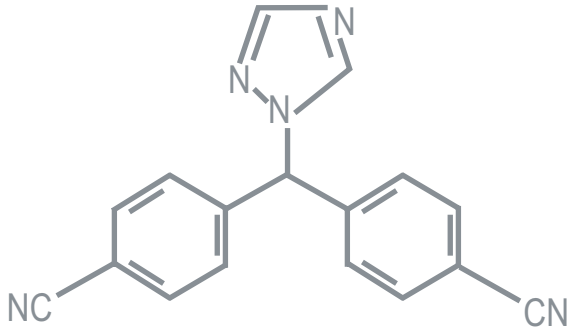
Letromina™ Tablets 2.5mg

Alpha · Pharma
healthcare

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 melabolite(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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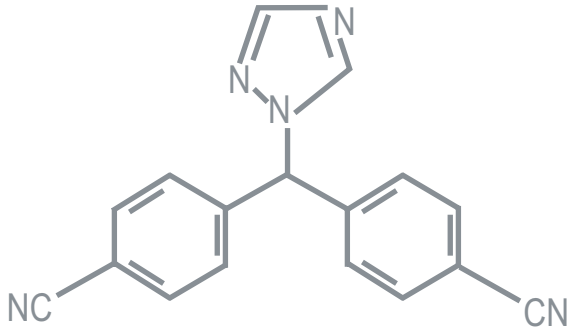

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INDICATIONS
Letromina™ is indicated for the following conditions :

- 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, vomitting, , 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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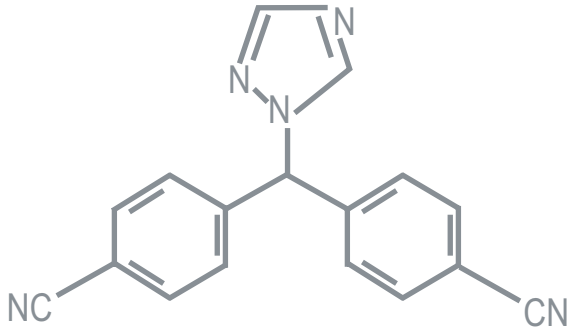

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DRUG INTERACTION
Clinical interaction studies with cimetidine and warfarin indicated that co-administration of Letrozole with these drugs does not result in clinically significant drug reactions, even though cimetidine is a known inhibitor of one of the cytochrome P450 isoenzymes capable of metabolising Letrozole in vitro.

Coadminstaration of Letrozole and tamoxifen 20 mg daily resulted in the reduction of letrozole plasma levels by 38% on average.

CONTRAINDICATIONS
Letromina™ should not be used in patients with known or suspected hypersensitivity to letrozole or any one of the tablet excipients or other aromatase inhibitors. It is contraindicated during pregnancy, lactation and in premenopausal women. It is also contraindicated in severe hepatic dysfunction

WARNING & PRECAUTIONS
In breast cancer patients with moderate hepatic dysfunction, no dosage adjustment is necessary, but caution is recommended since Letrozole elimination depends mainly on intrinsic metabolic clearance.

Renal impairment (calculated creatinine clearance: 20 to 50 ml/min) did not affect steady state plasma Letrozole concentration at a dose of 2.5 mg or 5 mg. Hence, no dose adjustment is necessary for such renal function impairment. It is anticipated that Letrozole could be removed from blood by dialysis since it is weakly bound to plasma proteins. On administration of letrozole, fatigue and dizziness has been observed in some cases, and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery, and any other activity requiring alertness.

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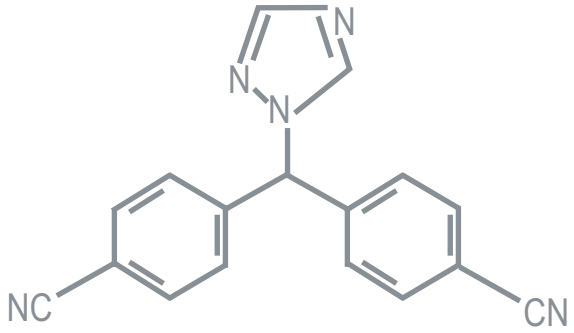

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OVERDOSAGE
There is no clinical experience of overdosage. There is no specific antidote to Letrozole.

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 tight. 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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