ONCOLOGY

Letrozole Kabi

Trusted Generics: Total Care

Letrozole Kabi
Film-Coated Tablets

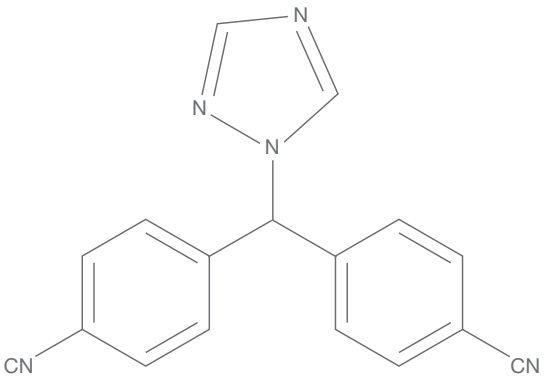
FRESENIUS KABI

caring for life

LETROZOLE KABI

Therapeutic class

Antineoplastic Agent; Aromatase Inhibitor



Indications

- First line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer
- For the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy

Composition

Each tablet contains 1 mg letrozole

Available Fresenius Kabi dosage forms

Strength is denoted by color

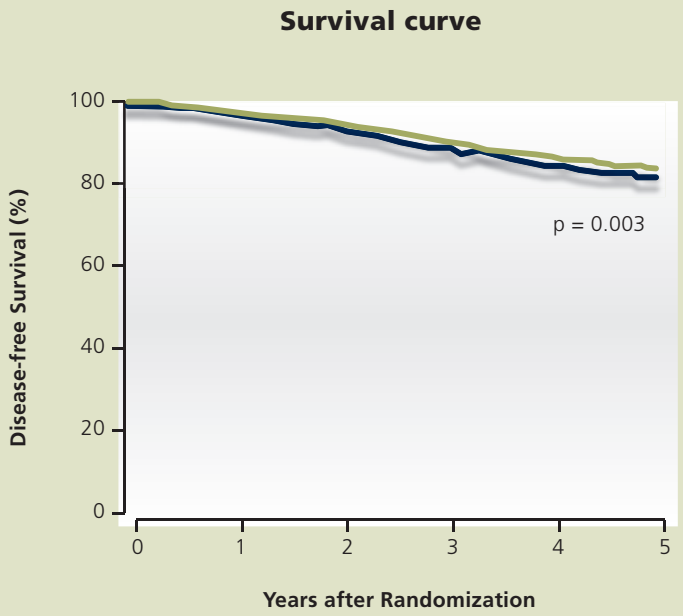
- 2.5 mg yellow biconvex film coated tablets, supplied in a strip of 10 or 14 tablets

Pack Size

- Letrozole Kabi 2.5 mg: 10/14/28/30/50//60/90 and 100 tablets

Letrozole in focus

- Proven third generation aromatase inhibitor
- Maximum inhibition of aromatase compared to other drugs
- Exerts its antitumor effect by depriving estrogen-dependant breast cancer cells of their growth stimulus
- Inhibits the aromatase enzyme by competitively binding to the cytochrome P450 subunit of the enzyme



Letrozole

No. at risk	4003	3892	2964	1261	892	567
Disease-free survival (%)		97.7	95.1	90.5	86.8	84.0

Tamoxifen

No. at risk	4007	3896	2926	1238	866	544
Disease-free survival (%)		97.6	93.4	89.0	84.6	81.4

Kaplan-Meier estimates of disease free survival.

Dosage and administration

- The recommended dose of Trozet is a 2.5 mg tablet administered once a day
- Treatment should continue until tumor progression is evident
- No dose adjustment is required for elderly patients

Storage and handling

- Letrozole Kabi tablets should be stored at room temperature (15–30 °C)
- No special instructions for handling are required

Letrozole Kabi 2.5 mg Film-coated Tablets

Composition: Each film-coated tablet contains 2.5 mg letrozole. Each film-coated tablet contains 79.20 mg lactose monohydrate. **Therapeutic Indications:** Adjuvant treatment of post-menopausal women with hormone receptor-positive early breast cancer. Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women who have received prior standard adjuvant tamoxifen therapy for 5 years. First-line treatment in post-menopausal women with hormone-dependent advanced breast cancer. Advanced breast cancer in women with natural or artificially-induced post-menopausal status after relapse or disease progression, who have previously been treated with anti-oestrogens. Efficacy has not been demonstrated in patients with hormone receptor- negative breast cancer. **Dosage and administration:** Adult and elderly patients: The recommended dose of letrozole is 2.5 mg once daily. No dose adjustment is required for elderly patients. In the adjuvant setting, it is recommended to treat for 5 years or until tumor relapse occurs. In the adjuvant setting, clinical experience is available for 2 years (median duration of treatment was 25 months). In the extended adjuvant setting, clinical experience is available for 4 years (median duration of treatment). In patients with advanced or metastatic disease, treatment with letrozole should continue until tumor progression is evident. Children: Not applicable. Patients with hepatic and/or renal impairment: No dosage adjustment is required for patients with renal insufficiency with creatinine clearance greater than 30 ml/min. Insufficient data are available in cases of renal insufficiency with creatinine clearance lower than 30 ml/min or in patients with severe hepatic. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Pre-menopausal endocrine status; pregnancy; lactation. **Special warnings and precautions for use:** In patients whose post-menopausal status seems unclear, LH, FSH and/or estradiol levels must be assessed before initiating treatment in order to clearly establish menopausal status. Renal impairment: Letrozole has not been investigated in a sufficient number of patients with a creatinine clearance lower than 10 ml/min. The potential risk/benefit to such patients should be carefully considered before administration of letrozole. Hepatic impairment: Letrozole has only been studied in a limited number of non-metastatic patients with varying degrees of hepatic function: mild to moderate, and severe hepatic insufficiency. In non-cancer male volunteers with severe hepatic impairment (liver cirrhosis and Child-Pugh score C), systemic exposure and terminal half-life were increased 2-3-fold compared to healthy volunteers. Thus, letrozole should be administered with caution and after careful consideration of the potential risk/benefit to such patients. Bone Effects: Letrozole is a potent oestrogen-lowering agent. In the adjuvant and extended adjuvant setting the median follow-up duration of 30 and 49 months respectively is insufficient to fully assess the fracture risk associated with long-term use of letrozole. Women with a history of osteoporosis and/or fractures or who are at increased risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry prior to the commencement of adjuvant and extended adjuvant treatment and be monitored for development of osteoporosis during and following treatment with letrozole. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or of glucose-galactose malabsorption should not take this medicine.

Marketing Authorisation Holder:
Marketing Authorisation Number:

Registered product information may differ in your country. For further information, and before prescribing, refer to the nationally approved Summary of Product Characteristics (SmPC).

Month Year

FRESENIUS KABI
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