

## Regimen Monograph

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## A - Regimen Name

# LETR Regimen

Letrozole

**Disease Site**      Gynecologic  
Ovary

**Intent**              Palliative

**Regimen Category**      **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses**      For the treatment of ovarian cancer

**Supplementary Public Funding**      [letrozole](#)  
ODB - General Benefit (letrozole) ([ODB Formulary](#) )

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**B - Drug Regimen****[letrozole](#)**

2.5 mg

PO

Daily

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Until disease progression or unacceptable toxicity.

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**Antiemetic Regimen:** Not applicable

**Other Supportive Care:**

- Assess patient's risk factors for osteoporosis and consider calcium and vitamin D supplements and bisphosphonates where appropriate. Refer patients to the [Bone Health During Cancer Treatment](#) pamphlet for more information.

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**E - Dose Modifications**

Doses should be modified according to the protocol by which the patient is being treated.

**Dosage with toxicity**

Dosage in myelosuppression: No dosage adjustment required.

**Hepatic Impairment**

<b>Hepatic Impairment</b>	<b>Letrozole Dose</b>
Mild to Moderate (Child-Pugh Class A or Class B)	No dose adjustment needed, although exposure may ↑ by 37%.
Severe (Child-Pugh C)	No data. Monitor patients closely and consider dose modification.

**Renal Impairment**

<b>Creatinine Clearance (mL/min)</b>	<b>Letrozole Dose</b>
≥ 10	No dose adjustment needed.
< 10	No data. Consider potential benefit-risk carefully.

**Dosage in the Elderly**

No dosage adjustment required. Older patients have an increased risk of osteoporosis and fracture.

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**F - Adverse Effects**

Refer to [letrozole](#) drug monograph(s) for additional details of adverse effects.

<b>Very common (≥ 50%)</b>	<b>Common (25-49%)</b>	<b>Less common (10-24%)</b>	<b>Uncommon (&lt; 10%), but may be severe or life-threatening</b>
<ul style="list-style-type: none"><li>• Estrogen deprivation symptoms</li></ul>	<ul style="list-style-type: none"><li>• Fatigue</li><li>• Headache, musculoskeletal pain</li><li>• Edema</li></ul>	<ul style="list-style-type: none"><li>• ↑ Cholesterol</li><li>• Dizziness</li><li>• Constipation</li><li>• Nausea, vomiting</li><li>• Osteoporosis, fracture</li></ul>	<ul style="list-style-type: none"><li>• Arterial thromboembolism</li><li>• Venous thromboembolism</li><li>• Arrhythmia</li><li>• Cardiotoxicity</li><li>• Cataracts</li><li>• Hypersensitivity</li><li>• Rash</li></ul>

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**G - Interactions**

Refer to [letrozole](#) drug monograph(s) for additional details.

- Avoid concomitant use with tamoxifen, other anti-estrogens, estrogen-containing or estrogenic therapies due to the risk of decreased letrozole efficacy.

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## H - Drug Administration and Special Precautions

Refer to [letrozole](#) drug monograph(s) for additional details.

### Administration:

- Tablets should be taken with a glass of water, with or without food, at around the same time every day.
- Tablets should not be crushed or chewed.
- Missed doses should be taken as soon as possible, but should be skipped if within a few hours (e.g. within 2 or 3 hours) of the next planned dose. Do not double the dose due to over-proportionality of exposure at doses above 2.5 mg daily.
- Store tablets at room temperature (15-30°C).

### Contraindications:

- Patients with known hypersensitivity to letrozole, or any of its components, or other aromatase inhibitors.
- Premenopausal women\*
- Pregnant and/or breastfeeding women
- Patients under 18 years of age

*\*not receiving ovarian suppression*

### Warnings/Precautions:

- Letrozole is not indicated in hormone-receptor negative disease.
- Some brands contain lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

### Pregnancy/Lactation:

- This regimen is **contraindicated** for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is **contraindicated** during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Probable

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## I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

### Recommended Clinical Monitoring

- Serum cholesterol and lipids evaluation; Baseline and as clinically indicated
- Bone mineral density; Baseline and as clinically indicated
- LH, FSH and/or estradiol levels (in patients whose menopausal status is unclear or who become amenorrheic after chemotherapy); Baseline and regularly during the first 6 months of treatment
- Clinical toxicity assessment of fatigue, estrogen deprivation symptoms, musculoskeletal, cardiovascular, thromboembolism, GI and GU effects, ophthalmic, dermatologic effects; At each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

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## J - Administrative Information

Outpatient prescription for home administration

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## K - References

Letrozole drug monograph. Ontario Health (Cancer Care Ontario).

Papadimitriou CA, Markaki S, Siapkarakas J, et al. Hormonal therapy with letrozole for relapsed epithelial ovarian cancer. Long-term results of a phase II study. *Oncology*. 2004;66(2):112-7.

Ramirez PT, Schmeler KM, Milam MR, et al. Efficacy of letrozole in the treatment of recurrent platinum- and taxane-resistant high-grade cancer of the ovary or peritoneum. *Gynecol Oncol*. 2008 Jul;110(1):56-9.

## PEBC Advice Documents or Guidelines

- [Systemic Therapy for Recurrent Epithelial Ovarian Cancer](#)

**August 2025** Updated Pregnancy/Lactation section

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## M - Disclaimer

### Regimen Abstracts

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

*Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.*

### Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

*The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is*

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*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

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