

Regimen Monograph

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A - Regimen Name

LPRL Regimen

Leuprolide

Disease Site Breast

Intent Adjuvant
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 hormone receptor positive breast cancer in pre or peri-menopausal women.

Supplementary Public Funding [leuprolide](#)
ODB - General Benefit (leuprolide - long-acting formulation) ([ODB Formulary](#))

[leuprolide](#)
ODB - General Benefit (leuprolide - long-acting formulation)

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B - Drug Regimen

leuprolide	22.5 mg	IM	Day 1 of Q3M
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OR

leuprolide	7.5 mg	IM	Day 1 of QM
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22.5 MG - REPEAT EVERY 3 MONTHS

7.5 MG REPEAT EVERY MONTH

Until disease progression or unacceptable toxicity

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Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

Dosage with toxicity

Toxicity	Dose modification
Myelosuppression	No dose reduction needed
↑ LFTs	Hold until ≤ grade 1. If no recovery then discontinue
Arterial and venous thromboembolism	Discontinue

Pituitary apoplexy	Discontinue
Pneumonitis	Discontinue

Hepatic Impairment

No adjustment required

Renal Impairment

No adjustment required

Dosage in the Elderly

No adjustment required

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F - Adverse Effects

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

Very common ($\geq 50\%$)	Common (25-49%)	Less common (10-24%)	Uncommon ($< 10\%$), but may be severe or life-threatening
<ul style="list-style-type: none"> Estrogen deprivation symptoms (i.e. hot flashes) 	<ul style="list-style-type: none"> Musculoskeletal pain Injection site reactions 	<ul style="list-style-type: none"> Edema Fatigue Rash Headache 	<ul style="list-style-type: none"> Tumour flare Arrhythmia, QT prolongation Cardiotoxicity Arterial / venous thromboembolism Osteoporosis Pneumonitis Pituitary apoplexy

			<ul style="list-style-type: none"> • Seizures • Hypersensitivity • GI hemorrhage, obstruction • Mood changes, depression • Hepatotoxicity • Hyperglycemia • Increased creatinine
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G - Interactions

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

- Exercise caution when used with drugs that prolong the QT interval
- Leuprolide may interfere with diagnostic tests of pituitary-gonadal function; these tests should be conducted at more than 8 weeks after discontinuing treatment.

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H - Drug Administration and Special Precautions

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

Administration - Lupron Depot®

- Outpatient prescription; administer in Cancer Centre or physician's office
- Vary injection site
- For long-acting preparations, reconstitute with supplied diluent immediately before injection as directed (see product monograph).
- Do not give multiple monthly injections together to make up a q3 or q4 month dose, as the release characteristics are different.
- For Intramuscular use only
- Usual sites of injection include the anterior thigh, gluteal area or deltoid. Vary injection sites.
- Store at room temperature.

Contraindications and Precautions:

- Patients with hypersensitivity to the drug, its components or similar nonapeptides; Lupron® contains benzyl alcohol and may cause local reactions.
- Use with caution in patients with osteoporosis (or risk factors for osteoporosis), diabetes, risk factors for QT prolongation, history of depression, cardiovascular disease, in patients at risk of disease flare or convulsions.
- Adequate contraception (with non-hormonal methods) should be used by both sexes during treatment and up to 6 months after leuprolide cessation.

Pregnancy & Lactation:

Leuprolide is contraindicated in pregnancy and breastfeeding. Adequate contraception (with non-hormonal methods) should be used by both sexes during treatment and up to 6 months after leuprolide cessation.

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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

- Blood glucose levels/HbA1c; baseline and periodic, especially in diabetic patients
- EKG, Electrolytes, (including K, Ca, Mg); baseline, also regular for at risk patients
- Liver function tests; periodic
- Clinical assessment of disease flare, local reactions, thromboembolism, cardiovascular effects, osteoporosis, psychiatric effects, hot flashes and injection site reactions; at each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

Suggested Clinical Monitoring

- Renal function tests; periodic

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J - Administrative Information

Outpatient prescription; drug administration at Cancer Centre or physician's office

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K - References

Francis, P et al. Adjuvant ovarian suppression in premenopausal breast cancer. N Engl J Med. 2015;372:436-46.

Kendzierski, DC et al. Efficacy of different leuprolide administration schedules in premenopausal breast cancer: a retrospective review. Clin breast cancer. 2018;5; 939-942.

Leuprolide drug monograph, Cancer Care Ontario.

Schmid P, Untch M, Kossé V, Bondar G, Vassiljev L. Leuprorelin acetate every-3-months depot versus cyclophosphamide, methotrexate, and fluorouracil as adjuvant treatment in premenopausal patients with node-positive breast cancer: the TABLE study. J Clin Oncol. 2007 Jun 20;25(18):2509-15.

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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

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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.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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