Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

EXEM Regimen

Exemestane

Disease Site	Breast Gynecologic - Endometrial
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 hormonal treatment of advanced breast cancer in postmenopausal women with estrogen receptor-positive tumours, whose disease have progressed following anti-estrogen therapy • For the treatment of advanced endometrial cancer
Supplementary Public Funding	**exemestane** ODB - General Benefit (exemestane) (ODB Formulary)

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B - Drug Regimen

exemestane	25 mg	PO	Daily

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C - Cycle Frequency

CONTINUOUS TREATMENT

Until evidence of disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

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

Toxicity	Exemestane Dose
Myelosuppression	No adjustment required.
Severe cutaneous reactions or acute generalized exanthematus pustulosis (AGEP)	Discontinue permanently.

Hepatic Impairment

Although AUC is tripled in the presence of liver impairment (Child-Pugh C), adverse effects are not increased. No dosage adjustment is required.

Renal Impairment

Although AUC is tripled in the presence of severe renal impairment (CrCl < 30 mL/min), adverse effects are not increased. No dosage adjustment is required.

Dosage in the Elderly

No dosage adjustment is required.

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F - Adverse Effects

Refer to exemestane drug monograph(s) for additional details of adverse effects.

Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Estrogen deprivation symptoms • Musculoskeletal pain • Fatigue • ↑ LFTs (may be severe) • Alopecia • Headache • Insomnia • Hypertension • Dizziness	• Cardiotoxicity • Arterial thromboembolism • Venous thromboembolism • Secondary malignancies • Osteoporosis/fractures • Hypersensitivity • Rash • GI ulcer • ↑ cholesterol

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G - Interactions

Refer to exemestane drug monograph(s) for additional details.

- Avoid concomitant use of estrogen-containing or estrogenic agents due to ↓ effect of exemestane.
- Monitor PT/INR of patients on warfarin switching from tamoxifen to exemestane due to possible INR level changes.

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H - Drug Administration and Special Precautions

Refer to exemestane drug monograph(s) for additional details.

Administration

- Tablets should be swallowed whole with a glass of water after a meal (to enhance absorption).
- Store tablets at room temperature (15-30°C).

Contraindications

- Patients with known hypersensitivity to exemestane or any of its components

Warning/Precautions

- Use is not recommended in pre-menopausal women*.
- Patients with pre-existing severe osteoporosis, a history of osteoporotic fracture or significant cardiac disorders were excluded from clinical trials in early breast cancer.
- Exemestane may increase risk of gastric ulcers especially in patients on NSAIDs and/or with a prior history.

**not receiving ovarian suppression*

Pregnancy and Lactation

- Exemestane is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment, and for at least **6 months** (general recommendation) after the last dose.
- Breastfeeding is not recommended during treatment.
- 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

- Bone mineral density; Baseline and as clinically indicated
- Cholesterol and lipids evaluation; Baseline and as clinically indicated
- Clinical assessment of estrogen deprivation symptoms, fatigue, cardiovascular, musculoskeletal, thromboembolism, hypersensitivity, skin and GI effects; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- CBC; Baseline and as clinically indicated
- Liver and renal function tests; Baseline and as clinically indicated
- INR for patients on warfarin (when switching from tamoxifen to exemestane); As clinically indicated

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J - Administrative Information

Outpatient prescription for home administration

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K - References

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

Breast:

Kaufmann M, Bajetta E, Dirix L et al. Exemestane is superior to megestrol acetate after tamoxifen failure in postmenopausal women with advanced breast cancer: results of a phase III randomised double-blind trial. J Clin Oncol 2000;18:1399-411.

Lonning PE, Bajetta E, Murray R, et al. Activity of exemestane in metastatic breast cancer after failure of nonsteroidal aromatase inhibitors: a phase II trial. J Clin Oncol 2000;18(11):2234-44.

Endometrial:

Ethier JL, Desautels DN, Amir E, MacKay H. Is hormonal therapy effective in advanced endometrial cancer? A systematic review and meta-analysis. Gynecologic Oncology 2017;147:158-166.

Lindemann K, Malander S, Christensen RD. Exemestane in advanced or recurrent endometrial carcinoma: a prospective phase 2 study by the Nordic Society of Gynecologic Oncology (NSGO). BMC Cancer 2014, 14:68. http://www.biomedcentral.com/1471-2407/14/68

November 2020 Added endometrial cancer as an ST-QBP approved indication; Updated dose modifications, adverse effects, interactions, drug administration and special precautions, and clinical monitoring sections

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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.

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