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

ANAS Regimen

Anastrozole

Disease Site	Breast
Intent	Adjuvant
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 adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer* *Aromatase inhibitors (AIs) have been used in the neoadjuvant setting in some clinical trials; AIs generally demonstrated higher breast conserving surgery rates with superior or similar response rates to tamoxifen. However, neoadjuvant AI use has not been approved by Health Canada.
Supplementary Public Funding	**anastrozole** ODB - General Benefit (anastrozole) (ODB Formulary)

back to top

B - Drug Regimen

anastrozole	1 mg	PO	Daily

back to top

C - Cycle Frequency

CONTINUOUS TREATMENT

Unless disease progression or unacceptable toxicity

Upfront treatment: For 5 years
Switch strategy: For 2-3 years (as a switch after 2-3 years of tamoxifen) for a total of 5 years of endocrine therapy
Extended adjuvant therapy: For 3-5 years, after completing 5 years of tamoxifen

back to top

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.

back to top

E - Dose Modifications

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

Dosage with toxicity

Toxicity	Action
Myelosuppression	No adjustment required.
Severe hypercalcemia	Hold; discontinue if recurs.

Hepatic Impairment

Clearance is reduced by 30% in patients with cirrhosis, but plasma levels are within normal range.

Hepatic Impairment	Anastrozole Dose
Mild to Moderate	No adjustment is required.
Severe	Not studied; consider potential risk/benefit.

Renal Impairment

Clearance is reduced by 50% in severe renal impairment. However, renal excretion is a minor route of excretion and no adjustment is required.

Creatinine Clearance (mL/min)	Anastrozole Dose
≥ 30	No adjustment is required.
< 30	No adjustment is required. Consider potential risk/benefit.

Dosage in the Elderly

No dosage adjustment required.

back to top

F - Adverse Effects

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

Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Estrogen deprivation symptoms • Musculoskeletal pain	• Fatigue • Mood changes (including depression) • Hypertension • Nausea, vomiting • Osteoporosis, fracture • Rash • Headache • Insomnia	• Arterial and venous thromboembolism • Ischemic cardiovascular events • Endometrial cancer • Hypercalcemia • Vasculitis • Hypersensitivity • Erythema multiforme • Stevens-Johnson syndrome • ↑ LFTs • Cataract

back to top

G - Interactions

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

- Do not co-administer with tamoxifen due to ↓ anastrozole concentration and no efficacy or safety benefit.
- Avoid estrogen-containing or estrogenic agents due to ↓ estrogen suppression.

back to top

H - Drug Administration and Special Precautions

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

Administration:

- Administer anastrozole with or without food.
- Tablets should be swallowed whole with a glass of water at the same time each day.
- Missed doses should be taken as soon as possible, but only if there are at least 12 hours before the next dose is due.
- Store at room temperature (15 to 30°C).

Contraindications:

- Patients with hypersensitivity to the drug or any of its components
- Pregnant or lactating women

Warnings/Precautions:

- Use is not recommended in premenopausal women*.
- Use with caution in patients with known osteoporosis or risk factors for osteoporosis, in patients with pre-existing cardiovascular disorders, severe liver or renal impairment.
- Anastrozole has not been studied in patients with brain, leptomeningeal or pulmonary lymphangitic disease.
- Use of formulations containing lactose should be carefully considered in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

**not receiving ovarian suppresion*

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

back to top

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 for patients at risk; Baseline and as clinically indicated
- Clinical toxicity assessment for fatigue, musculoskeletal, estrogen deprivation symptoms, mood changes (including depression), rash, edema, thromboembolism, cardiovascular, GI and GU effects; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Liver function tests; Baseline and as clinically indicated
- Electrolytes, including calcium; Baseline and as clinically indicated
- Cholesterol and lipid evaluation; Baseline and as clinically indicated

back to top

J - Administrative Information

Outpatient prescription for home administration

back to top

K - References

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

ATAC Trialists' Group. Results of the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial after completion of 5 years' adjuvant treatment for breast cancer. Lancet 2005; 365: 60-62.

ATAC Trialists' Group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: Results of the ATAC (Arimidex, Tamoxifen Alone or in Combination) Trial Efficacy and Safety Update Analyses. Cancer 2003; 98: 1802-1810.

ATAC Trialists' Group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial. Lancet. 2002 Jun 22;359(9324):2131-9.

Baum M, Budzar AU, Cuzick J, et al (ATAC Trialists Group). Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 100-month analysis of the ATAC trial. Lancet Oncology 2008; 9(1): 45-53.

Smith IE, Dowsett M, Ebbs SR, et al. Neoadjuvant treatment of postmenopausal breast cancer with anastrozole, tamoxifen, or both in combination: the Immediate Preoperative Anastrozole, Tamoxifen, or Combined with Tamoxifen (IMPACT) multicenter double-blind randomized trial. J Clin Oncol 2005;23(22):5108-16.

PEBC Advice Documents or Guidelines

- Optimal Systemic Therapy for Early Female Breast Cancer

April 2024 Updated Pregnancy and Lactation section

back to top

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 not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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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back to top