

## Regimen Monograph

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## A - Regimen Name

# TMXFRIBO Regimen

Tamoxifen - Ribociclib

**Disease Site** Breast

**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.

This **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). 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.

**Rationale and Uses** For the treatment of premenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as an initial endocrine-based therapy.

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

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<a href="#">tamoxifen</a>	20 mg	PO	Daily
<a href="#">ribociclib</a>	600 mg	PO	Days 1 to 21

(This drug is not currently publicly funded for this regimen and intent)

*Note: For premenopausal patients; must be given together with GnRH agonist*

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**Tamoxifen:** Continuous

**Ribociclib:** Every 28 days (3 weeks on, 1 week off)

Until disease progression or unacceptable toxicity

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**Antiemetic Regimen:** Minimal – No routine prophylaxis; PRN recommended

**Other Supportive Care:**

Also refer to [CCO Antiemetic Recommendations](#).

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Hortobagyi, G. N. et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. *New Engl. J. Med.* 375, 1738–1748 (2016).

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Hortobagyi GN, Stemmer SM, Burris HA, et al. Updated results from MONALEESA-2, a phase III trial of first-line ribociclib plus letrozole versus placebo plus letrozole in hormone receptor-positive, HER2-negative advanced breast cancer. *Ann Oncol* 2018;29:1541-1547.

Tripathy D, Im S, Colleoni M, et al. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor-positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial.

**May 2019** Updated emetic risk category

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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.*

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### **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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*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*

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*provider if they have questions regarding any information set out in the Formulary documents.*

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