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

FEC100 Regimen

Fluorouracil-EPIrubicin-Cyclophosphamide

Disease Site	Breast
Intent	Adjuvant Neoadjuvant
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	Neo-adjuvant or adjuvant therapy for node-positive and high risk node-negative early breast cancer

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B - Drug Regimen

fluorouracil	500 mg /m²	IV	Day 1
EPIrubicin	100 mg /m²	IV	Day 1
cyclophosphamide	500 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a usual total of 6 cycles unless disease progression or unacceptable toxicity occurs

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Febrile Neutropenia Risk: Moderate

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E - Dose Modifications

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

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. Refer to the DPD Deficiency Guidance for Clinicians for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if grade 2-4 acute toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

Dosage with toxicity

Toxicity Type / Counts x 10^9/L		Toxicity Type / Counts x 10^9/L	Fluorouracil (% previous dose)	Epirubicin (% previous dose)	Cyclophosphamide (% previous dose)
ANC <1.5	Or	Platelet < 100	Hold *		
Febrile Neutropenia, Or Grade 4 ANC ≥ 7 d	Or	Thrombocytopenic bleeding	Hold *, then 75% (or consider GCSF – for isolated neutropenia)		
ANC ≥ 1.5	And	Platelet ≥ 100	100%		
Cardiotoxicity**			Discontinue	Discontinue	Caution
Grade 3 related organ / non-hematologic			*75% for suspect drug(s)		
Grade 4 related organ / non-hematologic			Discontinue		

*Retreat when toxicities have recovered to ≤ grade 2, platelets ≥ 100 x 10^9/L, and ANC ≥ 1.5 x 10^9/L.
**including any signs and symptoms of heart failure, greater than 10% decline in LVEF to below the lower limit of normal, a greater than 20% decline in LVEF from any level, or LVEF ≤ 45%.

Hepatic Impairment

AST/ALT		Bilirubin	Epirubicin (% previous)	Fluorouracil (% previous)	Cyclophosphamide (% previous)
2-4 x ULN	Or	1-2 x ULN	50%	No change	No change
>4 X ULN	Or	2-4 X ULN	25%	No change	Caution
		> 4 X ULN	Discontinue	Discontinue	Caution

Renal Impairment

CrCl (mL/min)	Fluorouracil	Epirubicin	Cyclophosphamide (% previous dose)
>30 – 50	100%	100%	100%
10 – 30	consider dose ↓		50-75%
< 10	↓ dose		50% or OMIT

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F - Adverse Effects

Refer to fluorouracil, EPIrubicin, cyclophosphamide drug monograph(s) for additional details of adverse effects

Bolus 5FU regimens have more myelosuppression and GI effects but less Hand-Foot Syndrome, compared to prolonged infusions.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Nausea and vomiting • Cystitis • Myelosuppression ± infection • Stomatitis and diarrhea • Alopecia • Fatigue • Amenorrhea	• Pneumonitis, pulmonary fibrosis • SIADH, renal failure • DIC, hemolytic uremic syndrome • Secondary leukemia or cancers • Venous/arterial thromboembolism • Cardiotoxicity, AMI, arrhythmia

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G - Interactions

Refer to fluorouracil, EPIrubicin, cyclophosphamide drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to fluorouracil, EPIrubicin, cyclophosphamide drug monograph(s) for additional details

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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

- CBC; baseline and before each cycle
- Baseline and regular liver and renal function tests and urinalysis
- Cardiac examination especially with risk factors (including prior therapy with doxorubicin, mitoxantrone or other cardiac drug), or a cumulative epirubicin dose of > 900mg/m^2
- Clinical toxicity assessment (including stomatitis, infection, cardiotoxicity, pulmonary, local toxicity, cystitis); at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	1.5 hours
Pharmacy Workload (average time per visit)	33.915 minutes
Nursing Workload (average time per visit)	61.667 minutes

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K - References

French Adjuvant Study Group. Benefit of a high-dose epirubicin regimen in adjuvant chemotherapy for node-positive breast cancer patients with poor prognostic factors: 5-year follow –up results of French Adjuvant Study group 05 randomized trial. J Clin Oncol 2001;19(3):602-11.

PEBC Advice Documents or Guidelines

- Optimal Systemic Therapy for Early Female Breast Cancer

April 2023 Updated DPD deficiency information in the Dose Modifications 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.

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

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