**FEC50 Regimen**

*Fluorouracil-EPIrubicin-Cyclophosphamide*

**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.

**Rationale and Uses**
Treatment of advanced breast cancer

**B - Drug Regimen**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>fluorouracil</strong></td>
<td>500 mg /m²</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>(Round to nearest 25 mg)</td>
<td></td>
<td></td>
<td>Day 1</td>
</tr>
<tr>
<td><strong>EPIrubicin</strong></td>
<td>50 mg /m²</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>(Round to nearest 1 mg)</td>
<td></td>
<td></td>
<td>Day 1</td>
</tr>
</tbody>
</table>
**cyclophosphamide**
(Round to nearest 10 mg)

500 mg /m² IV Day 1

C - Cycle Frequency

**REPEAT EVERY 21 DAYS**

Until disease progression or unacceptable toxicity

D - Premedication and Supportive Measures

**Antiemetic Regimen:** High

**Other Supportive Care:**

Also refer to [CCO Antiemetic Summary](#)

E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations are in use at some centres.

**Dosage with toxicity**

**Hematologic Toxicities:** See Appendix 6 for general recommendations.

<table>
<thead>
<tr>
<th>Worst Toxicity in Prior Cycle (Toxicity Type / Counts x 10⁹/L)</th>
<th>Fluorouracil (% previous dose)</th>
<th>Epirubicin (% previous dose)</th>
<th>Cyclophosphamide (% previous dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile Neutropenia, or Thrombocytopenic</td>
<td>75% *</td>
<td>75% *</td>
<td>75% *</td>
</tr>
</tbody>
</table>
bleeding, or
Grade 4 ANC ≥ 7 d
Cardiotoxicity ** Discontinue Discontinue Caution
Grade 3 related non-
hematologic/ organ 75% for suspect drug(s)*
Grade 4 related non-
hematologic/organ Discontinue

*Do not retreat until toxicity has recovered to ≤ grade 2, and 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

<table>
<thead>
<tr>
<th>AST/ALT</th>
<th>Bilirubin (% previous)</th>
<th>Epirubicin (% previous)</th>
<th>Fluorouracil (% previous)</th>
<th>Cyclophosphamide (% previous)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-4 x ULN</td>
<td>Or 1-2 x ULN</td>
<td>50%</td>
<td>No change</td>
<td>No change</td>
</tr>
<tr>
<td>&gt;4 X ULN</td>
<td>Or 2-4 X ULN</td>
<td>25%</td>
<td>No change</td>
<td>Caution</td>
</tr>
<tr>
<td></td>
<td>&gt; 4 X ULN</td>
<td>Discontinue</td>
<td>Discontinue</td>
<td>Caution</td>
</tr>
</tbody>
</table>

Renal Impairment

<table>
<thead>
<tr>
<th>Creatinine Clearance (mL/min)</th>
<th>Cyclophosphamide (% previous dose)</th>
<th>Fluorouracil (% previous dose)</th>
<th>Epirubicin (% previous dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;30-50</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>10-30</td>
<td>50-75%</td>
<td>Consider ↓ dose</td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>50% or OMIT</td>
<td>↓ dose</td>
<td></td>
</tr>
</tbody>
</table>

F - Adverse Effects

Refer to fluorouracil, EPIrubicin, cyclophosphamide drug monograph(s) for additional details of adverse effects
### Most Common Side Effects
- Nausea and vomiting
- Cystitis
- Myelosuppression ± infection, bleeding
- Stomatitis and diarrhea
- Alopecia
- Anorexia, fatigue
- Fever
- ↑ LFTs
- Rash, hand-foot syndrome, photosensitivity
- Conjunctivitis

### Less Common Side Effects, but may be Severe or Life-Threatening
- Pneumonitis
- SIADH, renal failure, VOD
- DIC, hemolytic uremic syndrome, hemolysis
- Secondary malignancies
- Venous/arterial thromboembolism
- Cardiotoxicity, AMI, arrhythmia
- Rhabdomyolysis
- Pancreatitis

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#### G - Interactions

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

#### H - Drug Administration and Special Precautions

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

#### 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
- Liver and renal function tests; baseline and before each cycle
- Cardiac examination especially with risk factors (including prior therapy with doxorubicin, mitoxantrone, or other cardiotoxic drug), or a cumulative cardiotoxic drug dose of > 900mg/m²; baseline and as clinically indicated
• Clinical toxicity assessment (including GI, infection, cardiotoxicity, pulmonary, local toxicity, cystitis); at each visit

• Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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

K - References

Cyclophosphamide, epirubicin, fluorouracil drug monographs, Cancer Care Ontario.


May 2016 removed subsite (already under intent)
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