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

TOPO Regimen

Topotecan

Disease Site	Gynecologic - Ovary
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 recurrent ovarian cancer

back to top

B - Drug Regimen

topotecan	1.25 - 1.5 mg /m²	IV	Days 1 to 5

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until evidence of disease progression or unacceptable toxicity

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Low

back to top

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.

Prior to administration of the first course of topotecan, patients must have a baseline neutrophil count of ≥ 1.5 x 10^9/L, a platelet count of > 100 x 10^9/L, and a hemoglobin level of ≥90 g/L.

Dosage with toxicity

Dose levels: 1.5 mg/m^2, 1.25 mg/m^2, 1 mg/m^2

Worst Toxicity Previous Cycle	Action[1]
Grade 4 neutropenia ≥ 7 days	Reduce dose by 1 dose level OR Use G-CSF with next cycle
Febrile neutropenia	
Cycle delay for hematologic toxicity	
Platelets <25 x 10^9/L	Reduce dose by 1 dose level
Grade 3 GI or organ toxicity	
Symptoms suggestive of pneumonitis	Hold and manage patient appropriately. Discontinue if confirmed.
Grade 4 GI or organ toxicity	Discontinue

1. Do not retreat until neutrophils ≥ 1 x 10^9/L, platelets ≥ 100 x 10^9/L, hemoglobin ≥90 g/L (after transfusion if necessary), and other toxicity ≤ grade 2.	

Hepatic Impairment

No dosage adjustment is required for treating patients with bilirubin < 171 µmol/L. Total topotecan clearance in patients with hepatic impairment only decreased by about 10%, as compared to the control group of patients.

Renal Impairment

Creatinine Clearance (mL/min)	% Usual dose
20 – 39	**REDUCE** Topotecan to **50 %** dose
< 20	**CONTRAINDICATED**

back to top

F - Adverse Effects

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

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Myelosuppression ± infection and bleeding (may be severe) • Alopecia • Diarrhea (may be severe) • Constipation, abdominal pain • Mucositis • Nausea and vomiting • Dyspnea/cough (may be severe) • Anorexia • Headache, pain • Rash (may be severe) • Fatigue	• Hypersensitivity • GI obstruction • Pneumonitis • ↑ LFTs

back to top

G - Interactions

Refer to topotecan drug monograph(s) for additional details

back to top

H - Drug Administration and Special Precautions

Refer to topotecan drug monograph(s) for additional details

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

- CBC; baseline and regular (must be assessed prior to each cycle)
- Liver and kidney function tests; baseline and regular
- Clinical toxicity assessment of GI, skin, infection, bleeding and pulmonary effects; at each visit

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

back to top

J - Administrative Information

Approximate Patient Visit	0.5 hour
Pharmacy Workload (average time per visit)	9.692 minutes
Nursing Workload (average time per visit)	36.667 minutes

back to top

K - References

Gordon AN, Tonda M, Sun S, et al. Long-term survival advantage for women treated with pegylated liposomal doxorubicin compared with topotecan in a phase 3 randomized study of recurrent and refractory epithelial ovarian cancer. Gynecol Oncol 2004;95(1):1-8.

Gordon A, Fleagle J Guthrie D et al. Recurrent epithelial ovarian carcinoma: a randomized phase III study of pegylated liposomal doxorubicin versus topotecan. J Clin Oncol 2001;19(14):3312-22.

Sehouli J, Stengel D, Oskay-Oezcelik G, et al. Nonplatinum topotecan combinations versus topotecan alone for recurrent ovarian cancer: results of a phase III study of the North-Eastern German Society of Gynecological Oncology Ovarian Cancer Study Group. J Clin Oncol 2008;26(19):3176-82.

ten Bokkel Huinink W, Lane SR, Ross GA. Long-term survival in a phase III, randomised study of topotecan versus paclitaxel in advanced epithelial ovarian carcinoma. Ann Oncol 2004;15(1):100-3.

Topotecan drug monograph, Cancer Care Ontario.

PEBC Advice Documents or Guidelines

- Systemic Therapy for Recurrent Epithelial Ovarian Cancer

August 2021 Modified Rationale and Uses 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.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary’s content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person’s use of the information in the Formulary.

back to top