Regimen Monograph

A - Regimen Name

CISPETOP(5D) Regimen

CISplatin-Etoposide

Disease Site	Gynecologic - Germ Cell
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 treatment of gynecological germ cell tumour.

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B - Drug Regimen

CISplatin	20 mg /m²	IV	Daily for 5 days

etoposide	100 mg /m²	IV	Daily for 5 days

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a Usual Total of 3 to 4 Cycles

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Febrile Neutropenia Risk: Moderate

Other Supportive Care:

Also refer to CCO Antiemetic Summary

Standard regimens for Cisplatin premedication and hydration should be followed. Refer to Cisplatin monograph

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. As this regimen is given for curative intent, supportive measures such as filgrastim may be appropriate rather than considering dose modifications. The following are recommendations when used in the palliative setting.

Dosage with toxicity

Hematologic Toxicities

Refer to Appendix 6 for general recommendations.

Hepatic Impairment

Bilirubin	ACTION
1. If Bilirubin 1-2 x ULN	**REDUCE** Etoposide to ***50%*** dose
2. If Bilirubin 2-4 x ULN	**REDUCE** Etoposide to ***25%*** dose
3. If Bilirubin > 4 x ULN	**OMIT** Etoposide (Suggested action)

Renal Impairment

Creatinine Clearance	ACTION
1. If CrCl = 15 – 50 mL/min	**REDUCE** Etoposide to ***75%*** dose
2. If CrCl = 30 – 60 mL/min or Serum Creatinine=136-185µmol/L	**REDUCE** Cisplatin* to ***50%*** dose
3. If CrCl < 30 mL/min or Serum Creatinine>185µmol/L	**OMIT** Cisplatin* dose
4. If CrCl < 15 mL/min	**REDUCE** Etoposide to ***50%*** dose

*Upon the discretion of the prescriber, less dose reduction may be suggested. See cisplatin drug monograph.

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F - Adverse Effects

Refer to CISplatin, etoposide drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Nausea, vomiting • Alopecia • Nephrotoxicity (may be severe) • Neurotoxicity (includes ototoxicity) • Myelosuppression +/- infection, bleeding • Anorexia • Diarrhea • Abnormal electrolytes	• ↑ LFTs • Hypersensitivity • Hypotension • Arterial thromboembolism • Venous thromboembolism • Pneumonitis • Seizure • Vasculitis

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G - Interactions

Refer to CISplatin, etoposide drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to CISplatin, etoposide 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

- Audiogram; Baseline and as clinically indicated
- Electrolytes, including magnesium, sodium, potassium, phosphate and calcium.; Baseline and regular
- Blood pressure; Baseline and at each treatment
- CBC; Baseline and regular
- Liver function tests; Baseline and regular
- Renal function tests; Baseline and regular
- Clinical toxicity assessment of infection, bleeding, nausea/vomiting, neurotoxicity, ototoxicity, thromboembolism; 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	2 to 3 hours
Pharmacy Workload (average time per visit)	15.79 minutes

Nursing Workload (average time per visit) 49.167 minutes

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K - References

Cisplatin and etoposide drug monographs, Cancer Care Ontario.

Gershenson DM. Management of Ovarian Germ Cell Tumors. J Clin Oncol 2007; 25:2938-2943.

Gershenson DM, Morris M, Cangir A, et al. Treatment of malignant germ cell tumours of the ovary with bleomycin, etoposide, and cisplatin. J Clin Oncol 1990; 8; 715-20.

Kang H, Kim TJ, Kim WY, et al. Outcome and reproductive function after high-dose combination chemotherapy with bleomycin, etoposide and cisplatin (BEP) for patients with ovarian endodermal sinus tumour. Gynecol Oncol 2008; 111(1): 106-10.

Pautier P, Gutierrez-Bonnaire M, Rey A, et al. Combination of bleomycin, etoposide, and cisplatin for the treatment of advanced ovarian granulose cell tumors. Int J Gynecol Cancer 2008; 18: 446–52.

Williams S, Blessing JA, Liao SY, et al. Adjuvant therapy of ovarian germ cell tumours with cisplatin, etoposide, and bleomycin: a trial of the Gynecologic Oncology Stroup. J Clin Oncol 1994; 12: 701-6.

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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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