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

DCTN Regimen

Dactinomycin

Disease Site	Gynecologic - Gestational Trophoblastic Disease
Intent	Curative
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 non-metastatic or metastatic Low Risk (WHO 0-4) GTN.

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B - Drug Regimen

DACTINomycin	1.25 mg /m²	IV (max. 2 mg)	Day 1

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C - Cycle Frequency

REPEAT EVERY 14 DAYS

Treatment continued one to two courses past the first normal hCG level, unless disease progression or unacceptable toxicity occurs.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Febrile Neutropenia Risk: Low

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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E - Dose Modifications

Dosage with toxicity

Doses should be modified according to the protocol by which the patient is being treated; if no guidelines available, refer to "Dosage Modification for Hematologic and Non-hematologic Toxicities".

Hold treatment if mucositis, pneumonitis, diarrhea or severe myelosuppression occurs.

Hepatic Impairment

Adjustment required in moderate to severe hepatic impairment; no specific recommendations found. May consider dose reduction by 33-50% in hyperbilirubinemia.

Renal Impairment

No adjustment required.

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F - Adverse Effects

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

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Diarrhea • Mucositis (may be severe) • Injection site reaction • Myelosuppression ± infection and bleeding (may be severe) • Nausea, vomiting (may be severe) • Fatigue	• Hypersensitivity • ↑LFT (may be severe) • Pneumonitis • Secondary malignancy • Veno-occlusive disease • Rash (may be severe)

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G - Interactions

Refer to DACTINomycin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to DACTINomycin 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

- Clinical assessment of GI, pneumonitis, skin, hepatic and local toxicity; at each visit
- CBC; baseline and regular
- Liver and renal function tests; baseline and periodic

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

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J - Administrative Information

Approximate Patient Visit	0.5 hours
Pharmacy Workload (average time per visit)	16.369 minutes
Nursing Workload (average time per visit)	41.667 minutes

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K - References

Dactinomycin drug monograph, Cancer Care Ontario.

Homesley HD. Development of single-agent chemotherapy regimens for gestation trophoblastic disease. J Reprod Med 1994 Mar; 39(3): 185- 92.

Society of Gynecologists and Obstetricians of Canada Clinical Practice Guidelines: Gestational Trophoblastic Disease

June 2020 Updated hyperlinks to dactinomycin drug monograph

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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.

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.

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