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

CISP(RT) Regimen

CISplatin (high dose)

Disease Site	Head and Neck
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	Postoperative adjuvant chemo-radiotherapy for locally advanced Head and Neck Cancer to improve control and survival outcomes for those patients at a high risk of recurrence who are willing and deemed able to tolerate the addition of chemotherapy to radiotherapy.

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B - Drug Regimen

CISplatin	100 mg /m²	IV	Days 1, 22, and 43

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C - Cycle Frequency

Single course concurrent with radiotherapy

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Febrile Neutropenia Risk: Low

Other Supportive Care:

For high dose Cisplatin administration ≥75mg/m², adequate hydration pre- and post-Cisplatin should be considered.

Also refer to CCO Antiemetic Summary

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and may be considered.

Dosage with toxicity

Hematologic Toxicities: See Appendix 6 for general recommendations.

Hepatic Impairment

No adjustment required.

Renal Impairment

Creatinine Clearance (mL/min)	Action
1. If CrCl = 0.5-1.0mL/sec or Serum Creatinine=136-185µmol/L	REDUCE Cisplatin* to 50% dose
2. If CrCl < 0.5mL/sec or Serum Creatinine>185µmol/L	OMIT Cisplatin 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 drug monograph(s) for additional details of adverse effects

Concurrent Cisplatin and radiotherapy can lead to moderate to severe stomatitis affecting oral intake while on treatment, hence consideration should be made for feeding tube insertion to maintain nutrition.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life Threatening
• Nausea and vomiting • Nephrotoxicity (may be severe), elecotrolyte abnormalities • Neurotoxicity and ototoxicity (may be severe), dysguesia • Myelosuppression ± infection / bleeding • Reproductive risk • Stomatitis	• Arterial thromboembolism • Arrythmia • Hemolytic uremic syndrome, vasculitis • SIADH • Myelopathy, optic neuritis • Leukemia • Seizures • Hypersensitivity

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G - Interactions

Refer to CISplatin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to CISplatin 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 toxicity assessment (including stomatitis, neurotoxicity and ototoxicity).
- CBC before each cycle
- Baseline and regular liver and renal function (including electrolytes and magnesium) tests.

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

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J - Administrative Information

Approximate Patient Visit	CISP(RT): 4-6 hours
Pharmacy Workload (average time per visit)	36.087 minutes
Nursing Workload (average time per visit)	41.667 minutes

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K - References

Bernier J, Domenge C, Ozsahin M, Matuszewska K, Lefebvre JL, Greiner RH. Postoperative

irradiation with or without concomitant chemotherapy for locally advanced head and neck cancer. N Engl J Med. 2004 May 6;350(19):1945-52.

Cisplatin drug monograph, Cancer Care Ontario.

Cooper JS, Pajak TF, Forastiere AA, Jacobs J, Campbell BH, Saxman SB. Postoperative concurrent radiotherapy and chemotherapy for high-risk squamous-cell carcinoma of the head and neck. N Engl J Med. 2004 May 6;350(19):1937-44

PEBC Advice Documents or Guidelines

- The Management of Head and Neck Cancer in Ontario
- Systemic Therapy in the Curative Treatment of Head and Neck Squamous Cell Cancer
- Chemotherapy with Radiotherapy for Nasopharyngeal Cancer

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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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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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