Regimen Monograph

A - Regimen Name

CISPDOXO Regimen

CISplatin-DOXOrubicin

Disease Site
Gynecologic - Uterine Sarcoma
Sarcoma - Uterine
(Mixed Mesodermal)

Intent
Adjuvant
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.

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B - Drug Regimen

CISplatin	50 mg /m²	IV	Day 1
DOXOrubicin	50 mg /m²	IV	Day 1

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a Usual Total of 6 Cycles or until evidence of disease progression or limited by drug toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: High

Febrile Neutropenia Risk: Moderate

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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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 are in use at some centres.

Dosage with toxicity

Hematologic Toxicities

Refer to Appendix 6 for general recommendations.

Hepatic Impairment

Bilirubin	Action
If Bilirubin 1-2 x ULN	**REDUCE** Doxorubicin to **50%** dose
If Bilirubin 2-4 x ULN	**REDUCE** Doxorubicin to **25%** dose
If Bilirubin > 4 x ULN	**OMIT** doses of Doxorubicin

Renal Impairment

Renal function	Action
If CrCl = 0.5-1.0mL/sec or Serum Creatinine=136-185µmol/L	**REDUCE** Cisplatin* to **50%** dose
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, DOXOrubicin 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/bleeding (may be severe) • Nausea and vomiting • Nephrotoxicity (may be severe) • Neurotoxicity and ototoxicity (may be severe) • Alopecia • Mucositis, diarrhea • Increased LFTs • Rash • Skin hyperpigmentation • Reproductive risk	• Arterial thromboembolism • Venous thromboembolism • Cardiotoxicity • Arrhthymia • Hemolytic uremic syndrome, hemolysis, vasculitis • Secondary malignancies • Vesicant • Photosensitivity • Hypersensitivity • Radiation recall reaction • Raynaud's

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G - Interactions

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

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H - Drug Administration and Special Precautions

Refer to CISplatin, DOXOrubicin 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

- CBC; Baseline and regular
- Liver function tests; Baseline and regular
- Renal function tests; Baseline and regular
- Electrolytes, including magnesium, sodium, potassium, phosphate and calcium.; Baseline and regular
- Cardiac function tests (Echo, RNA and/or MUGA scans) for all patients with cardiac risk factors (including prior trastuzumab or patients at or above threshold dose levels); Baseline and periodic
- Audiogram; Baseline and as clinically indicated
- Clinical toxicity assessment of infection, bleeding, nausea/vomiting, stomatitis, injection-site reactions, skin and cardiac toxicity, neurotoxicity, ototoxicity, thromboembolism; Regular

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

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J - Administrative Information

Approximate Patient Visit	4 hours
Pharmacy Workload (average time per visit)	37.002 minutes

Nursing Workload (average time per visit) 46.667 minutes

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K - References

Seltzer, V Kaplan B, Vogl S, et al. Doxorubicin and cisplatin in the treatment of advanced mixed mesodermal uterine sarcoma. Cancer Treatment Reports 1984; 68(11): 1389-90.

Peters WA 3rd, Rivkin SE, Smith MR, et al. Cisplatin and adriamycin combination chemotherapy for uterine stromal sarcomas and mixed mesodermal tumors. Gynecol Oncol 1989 Sep;34(3):323-7.

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L - Other Notes

Sarcomas are rare tumours and as such benefit from referral to specialized centres where there will be access to multidisciplinary expertise including good radiology, orthopedic and thoracic surgery, medical oncology, radiation oncology, pathology, and other supportive care disciplines.

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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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