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A		
REGIMEN NAME	PACLITAXEL Chemotherapy	
Cancer	Recurrent Ovarian Cancer	Palliative Intent
Regimen Category	Core, Restricted CCO: Standard therapy endorsed by the Disease Site Group and a regimen which requires eligibility confirmation for reimbursement by CCO New Drug Funding Program.	
Rationale and Uses	Treatment of platinum-sensitive recurrent ovarian cancer in patients, who cannot tolerate further platinum therapy or q3weekly paclitaxel	

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B			
DRUG REGIMEN			
PACLITAXEL (Round to nearest 3mg)	80 mg/m ² *	IV over 1 hour	Days 1, 8, 15 #
*Patients who experienced ≥ grade 3 hematologic or neurologic toxicities may start at 60 mg/m ² .			
# Some clinical trials have given paclitaxel on days 1, 8, 15, 22 for the first 3 cycles.			

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C	
CYCLE FREQUENCY	
REPEAT EVERY 28 DAYS	<i>Until disease progression or unacceptable toxicity</i>

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D**PREMEDICATION AND SUPPORTIVE MEASURES**

ANTIEMETIC REGIMEN:
[HESKETH LEVEL 2](#)

Patients should be pretreated with a corticosteroid as well as an antihistamine and a H2 Blocker:

For example:

DEXAMETHSONE 10 mg IV 30 minutes before Paclitaxel

DIPHENHYDRAMINE 50mg IV 30 minutes before Paclitaxel

RANITIDINE 50mg IV 30 minutes before Paclitaxel

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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.

Patients should not be retreated until neutrophil $\geq 1.5 \times 10^9/L$ and platelet counts $\geq 100 \times 10^9/L$.

Dose levels: 80 mg/m², 70 mg/m², 60 mg/m². Dose re-escalations are not allowed. Discontinue treatment if toxicity recurs after 2 dose reductions.

Toxicity (Grade or Counts x 10 ⁹ /L)	On Day 1 of cycle	On D8, 15 ± 22 of cycle ¹
	Paclitaxel dose	
ANC < 1.5 and/or Platelets < 100	Delay ¹	No change
ANC ≤ 0.5 and/or Platelets ≤ 75	Delay ¹ ; ↓ 1 level for next dose	OMIT, ↓ 1 level for next dose
≥ grade 2 renal / neurotoxicity	Delay ¹ ; ↓ 1 level	OMIT, ↓ 1 level for next dose
Other Grade 3 non-hematological ²	Delay ¹ ; ↓ 1 level	OMIT, ↓ 1 level for next dose
Grade 4 non-hematological	Discontinue	Discontinue

¹Delay for up to 2 weeks. Start day 1 of cycle when non-hematologic toxicities recover to ≤ grade 1, platelets $\geq 100 \times 10^9/L$, and ANC $\geq 1.5 \times 10^9/L$; reduce dose as per table.

²Except alopecia, fatigue, nausea. Appropriate symptom management should be provided for vomiting, diarrhea, constipation; dose modifications may not be necessary.

Hepatic Impairment

Bilirubin	AST/ALT	Paclitaxel dose (% previous dose)
1 – 3 x ULN		Caution
>3 - 4 x ULN	Grade 3	75% ¹ (or 70 mg/m ²)
> 4 x ULN	Grade 4	50% ¹ or OMIT

Consider dose modification for severe increases in LFTs.

¹Retreat when toxicities recover to ≤ grade 1, platelets $\geq 100 \times 10^9/L$, and ANC $\geq 1.5 \times 10^9/L$.

Renal Impairment

For Creatinine ≥ grade 2, may consider delay followed by ↓ 1 dose level.

F**ADVERSE EFFECTS**

Refer to the Paclitaxel drug monograph for full details of adverse effects.

Most Frequently Occurring Adverse Effects

- Myelosuppression ± infection (may be severe)
- Neurotoxicity
- Skin and nails (may be severe)
- Mucositis
- Fever
- Fatigue
- Nausea and vomiting
- Hypersensitivity reactions (may be severe)
- Myalgia and arthralgia
- Increases in LFTs
- Alopecia

Less Common but may be Severe or Life-Threatening

- Abnormal ECG, cardiac failure, acute MI
- Thromboembolism (venous)
- Pancreatitis, GI perforation/obstruction, typhlitis
- Pneumonitis, lung fibrosis

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G**INTERACTIONS**

Refer to the Paclitaxel drug monograph for full details.

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H**DRUG ADMINISTRATION AND SPECIAL PRECAUTIONS**

Refer to the Paclitaxel drug monograph for full details.

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I	CLINICAL MONITORING
	<ul style="list-style-type: none">• Clinical assessment of fever, infection, musculoskeletal, skin and nails, neurotoxicity, hypersensitivity and diarrhea. Grade toxicity using the current NCI Common Toxicity Criteria Version• CBC at baseline and before each cycle• Baseline and regular liver and renal function tests• Blood pressure and pulse rate monitoring during infusion, cardiac monitoring with prior arrhythmia

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J	ADMINISTRATIVE INFORMATION
Patients visit	Approximately 2 hours

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KEY REFERENCE(S)

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[CCO Practice Guideline:](#) The Optimal Chemotherapy Treatment for Women with Recurrent Ovarian Cancer

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