

Bladder/Urothelial small cell ciSplatin and etoposide

ID: 1725 v.5 Endorsed Essential Medicine List

This protocol is based on limited evidence; refer to the evidence section of this protocol for more information.

Check for clinical trials in this patient group. Link to Australian Clinical Trials website

The anticancer drug(s) in this protocol <u>may</u> have been included in the ADDIKD guideline. Dose recommendations in kidney dysfunction have yet to be updated to align with the ADDIKD guideline. Recommendations will be updated once the individual protocol has been evaluated by the reference committee. For further information refer to the ADDIKD guideline. To assist with calculations, use the <u>eviQ Estimated Glomerular Filtration Rate (eGFR) calculator</u>.

International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction (ADDIKD)

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2022

• Bladder/Urothelial small cell cARBOplatin and etoposide

Treatment schedule - Overview

Cycle 1 to 4

Drug	Dose	Route	Day
ciSplatin	75 mg/m ²	IV infusion	1
Etoposide *	120 mg/m ²	IV infusion	1 to 3

*Etopophos (etoposide phosphate) 113.6mg is equivalent to etoposide 100mg. Doses in this protocol are expressed as etoposide.

There is little evidence for etoposide dosing in this patient population, expert opinion agrees use of 120mg/m² in fit, healthy patients.

This regimen can be given concurrently with radiation therapy

Frequency:	21 days	
Cycles:	4 to 6 unless disease progression or unacceptable toxicity	
Drug status:	: All drugs in this protocol are on the PBS general schedule	
Cost:	~ \$490	

Treatment schedule - Detail

The supportive therapies (e.g. antiemetics, premedications, etc.), infusion times, diluents, volumes and routes of administration, if included, are listed as defaults. They may vary between institutions and can be substituted to reflect individual institutional policy.

Antiemetics if included in the treatment schedule are based upon recommendations from national and international guidelines. These are **defaults only** and may be substituted to reflect individual institutional policy. Select here for **recommended doses of alternative antiemetics**.

Cycle 1 to 4

Day 1		
Netupitant	300 mg (PO)	60 minutes before chemotherapy (fixed dose preparation with palonosetron)
Palonosetron	0.5 mg (PO)	60 minutes before chemotherapy (fixed dose preparation with netupitant)
Dexamethasone	12 mg (PO)	60 minutes before chemotherapy
ciSplatin	75 mg/m ² (IV infusion)	in 1000 mL sodium chloride 0.9% over 60 minutes
Etoposide	120 mg/m ² (IV infusion)	in 500 mL sodium chloride 0.9% over 30 to 60 minutes
Day 2 and 3		
Dexamethasone	8 mg (PO)	ONCE a day (or in divided doses) with or after food.
Etoposide	120 mg/m ² (IV infusion)	in 500 mL sodium chloride 0.9% over 30 to 60 minutes
Day 4		
Dexamethasone	8 mg (PO)	ONCE a day (or in divided doses) with or after food.

• Etopophos (etoposide phosphate) 113.6mg is equivalent to etoposide 100mg. Doses in this protocol are expressed as etoposide.

• There is little evidence for etoposide dosing in this patient population, expert opinion agrees use of 120mg/m² in fit, healthy patients.

Frequency: 21 days

Cycles: 4 to 6 unless disease progression or unacceptable toxicity

Indications and patient population

Indications:

- small cell bladder cancer
 - ECOG/WHO performance status 0 to 1

Exclusion:

• moderate/severe renal impairment (creatinine clearance less than 60 mL/min.).

Cautions:

- pre existing neuropathies
- significant hearing impairment/tinnitus
- ECOG/WHO performance status 2

Clinical information

Venous access required	IV cannula (IVC) or central venous access device (CVAD) is required to administer this treatment. Read more about central venous access device line selection
Hypersensitivity/infusion related reaction	High risk with etoposide.

Emetogenicity HIGH	Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy.
	Ensure that patients also have sufficient antiemetics for breakthrough emesis:
	Metoclopramide 10 mg three times a day when necessary (maximum of 30 mg/24 hours, up to 5 days) OR
	Prochlorperazine 10 mg PO every 6 hours when necessary.
	Read more about preventing anti-cancer therapy induced nausea and vomiting
Etoposide conversion factor	Note: Etopophos (etoposide phosphate) 113.6 mg is equivalent to etoposide 100 mg. Doses in this protocol are expressed as etoposide.
Hydration	Hydration helps to prevent cisplatin-induced nephrotoxicity.
	The default regimen is appropriate for patients with normal electrolytes, kidney function, fluid status etc. and should be adjusted according to individual requirements.
	Read more about cisplatin hydration regimens
Peripheral neuropathy	Assess prior to each treatment. If a patient experiences grade 2 or greater peripheral neuropathy, a dose reduction, delay, or omission of treatment may be required; review by medical officer before commencing treatment.
	Read more about peripheral neuropathy
	Link to chemotherapy-induced peripheral neuropathy screening tool
Ototoxicity	Ototoxicity may occur with platinum-based therapy; patients should be monitored for signs and symptoms. Platinum compounds should be used with caution in patients with pre-existing conditions or risk factors.
	Ototoxicity may become more severe in patients being treated with other drugs with nephrotoxic potential e.g. aminoglycosides.
	An audiometry test should be performed if symptoms develop.
	Read more about ototoxicity - tinnitus and hearing loss
Blood tests	FBC, EUC, LFTs, calcium and magnesium at baseline and prior to each cycle.
Hepatitis B screening and prophylaxis	Routine screening for HBsAg and anti-HBc is recommended prior to initiation of treatment. Prophylaxis should be determined according to individual institutional policy.
	Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy
Vaccinations	Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.
	Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook.
	Read more about COVID-19 vaccines and cancer.
Fertility, pregnancy and lactation	Cancer treatment can have harmful effects on fertility and this should be discussed with all patients of reproductive potential prior to commencing treatment. There is a risk of foetal harm
	in pregnant women. A pregnancy test should be considered prior to initiating treatment in females of reproductive potential if sexually active. It is important that all patients of reproductive potential use effective contraception whilst on therapy and after treatment
	finishes. Effective contraception methods and adequate contraception timeframe should be discussed with all patients of reproductive potential. Possibility of infant risk should be discussed with breastfeeding patients.
	Read more about the effect of cancer treatment on fertility
	Read more about the effect of cancer treatment on fertility

Dose modifications

Evidence for dose modifications is limited, and the recommendations made on eviQ are intended as a guide only. They are generally conservative with an emphasis on safety. Any dose modification should be based on clinical judgement, and the individual patient's situation including but not limited to treatment intent (curative vs palliative), the anti-cancer regimen (single

versus combination therapy versus chemotherapy versus immunotherapy), biology of the cancer (site, size, mutations, metastases), other treatment related side effects, additional co-morbidities, performance status and patient preferences.Suggested dose modifications are based on clinical trial findings, product information, published guidelines and reference committee consensus. The dose reduction applies to each individual dose and not to the total number of days or duration of treatment cycle unless stated otherwise. Non-haematological gradings are based on Common Terminology Criteria for Adverse Events (CTCAE) unless otherwise specified. Renal and hepatic dose modifications have been standardised where possible. For more information see dosing considerations & disclaimer.

The dose recommendations in kidney dysfunction (i.e.renal impairment) displayed may not reflect those in the ADDIKD guideline and have been included for historical reference only. Recommendations will be updated once the individual protocol has been evaluated by the reference committee, with this version of the protocol then being archived. Clinicians are expected to refer to the ADDIKD guideline prior to prescribing in kidney dysfunction.

International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction (ADDIKD).

Haematological toxicity		
ANC x 10 ⁹ /L (pre-treatment blood test)		
0.5 to less than 1.0	Delay treatment until recovery	
less than 0.5	Delay treatment until recovery and consider reducing cisplatin and etoposide by 25% for subsequent cycles	
Febrile neutropenia	Delay treatment until recovery and consider reducing cisplatin and etoposide by 25% for subsequent cycles	
Platelets x 10 ⁹ /L (pre-treatment blod test)		
75 to less than 100	Refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if patient is clinically well.	
50 to less than 75	Delay treatment until recovery	
less than 50	Delay treatment until recovery and consider reducing cisplatin and etoposide by 25% for subsequent cycles	

Renal impairment		
eGFR (CKI-EPI or MDRD) or eCrCl (Cockcroft Gault) (mL/min) *		
greater than or equal to 70	No dose modifications necessary	
50 to less than 70	Reduce cisplatin by 25%	
30 to less than 50	Reduce etoposide by 25% and cisplatin by 50% or consider substituting carboplatin for cisplatin	
less than 30	Reduce etoposide by 50% and omit cisplatin or consider substituting carboplatin for cisplatin	

* Each method has its limitations; refer to Nephrotoxicity associated with cisplatin for more information.

Hepatic impairment		
Hepatic dysfunction		
Mild	Reduce etoposide by 25%	
Moderate	Reduce etoposide by 50%	
Severe	Omit etoposide	
Peripheral neuropathy		
<u>r enprierar neuropaury</u>		
Grade 2 , Grade 3 or Grade 4	Omit cisplatin; consider substituting carboplatin for cisplatin	

Mucositis and stomatitis		
Grade 2	Delay treatment until toxicity has resolved to Grade 1 or less and reduce doses for subsequent cycles as follows: 1 st occurrence: No dose reduction 2 nd occurrence: Reduce cisplatin and etoposide by 25% 3 rd occurrence: Reduce cisplatin and etoposide by 50% 4 th occurrence: Omit cisplatin and etoposide	
Grade 3 or Grade 4	Delay treatment until toxicity has resolved to Grade 1 or less and reduce doses for subsequent cycles as follows: 1 st occurrence: Reduce cisplatin and etoposide by 50% 2 nd occurrence: Omit cisplatin and etoposide	

Interactions

Drug interactions in eviQ protocols are under review and being updated to align with current literature. Further site-wide updates and changes will occur in due course. References & Disclaimer

The drug interactions shown below are not an exhaustive list. For a more comprehensive list and for detailed information on specific drug interactions and clinical management, please refer to the specific drug product information and the following key resources:

- MIMS interactions tab (includes link to a CYP-450 table) (login required)
- Australian Medicines Handbook (AMH) interactions tab (login required)
- Micromedex Drug Interactions (login required)
- Cancer Drug Interactions
- Cytochrome P450 Drug Interactions

Cisplatin

	Interaction	Clinical management
Nephrotoxic drugs (e.g. aminoglycosides, amphotericin, contrast dye, frusemide, NSAIDs)	Additive nephrotoxicity	Avoid combination or monitor kidney function closely
Ototoxic drugs (e.g. aminoglycosides, frusemide, NSAIDs)	Additive ototoxicity	Avoid combination or perform regular audiometric testing
Neurotoxic drugs (e.g. vincristine, paclitaxel)	Additive neurotoxicity	Monitor closely for neuropathy if combination used
Paclitaxel	Administration schedule may influence the development of myelosuppression	Minimise toxicity by administering paclitaxel first in regimens using the combination
Carbamazepine, phenytoin, valproate	Decreased antiepileptic plasma levels	Monitor antiepileptic serum levels and seizure frequency for efficacy; adjust dosage as appropriate or select alternative antiepileptic (e.g. clonazepam, diazepam, lorazepam)

Etoposide and Etoposide Phosphate			
	Interaction	Clinical management	
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole- antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin etc.)	Increased toxicity of etoposide possible due to reduced clearance	Avoid combination or monitor for etoposide toxicity	
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of etoposide possible due to increased clearance	Avoid combination or monitor for decreased clinical response to etoposide	
Glucosamine	Reduced efficacy of etoposide (due to induction of glucose-regulated stress proteins resulting in decreased expression of topoisomerase II)	Avoid combination or monitor for decreased clinical response to etoposide	
Grapefruit juice	Reduced efficacy of oral etoposide possible due to possible alteration of P- gp mediated intestinal transport of etoposide	Avoid combination or monitor for decreased clinical response to etoposide	

NK-1 antagonist e.g. aprepitant, fosaprepitant, netupitant						
	Interaction	Clinical management				
Dexamethasone	Increased effects/toxicity of dexamethasone due to inhibition of its metabolism via CYP3A4	Reduce dose of antiemetic dexamethasone by approximately 50% when adding a NK-1 antagonist. For protocols that already recommend a NK- 1 antagonist, the dose reduction of antiemetic dexamethasone has already been taken into account. If dexamethasone is part of the chemotherapy protocol , dose reduction as per the product information is not routinely recommended in clinical practice and no additional dexamethasone is required for antiemetic cover.				
Warfarin	Reduced anticoagulant efficacy of warfarin due to increased clearance (aprepitant induces CYP2C9). *Note interaction only applicable to aprepitant/ fosaprepitant	INR should be monitored in the 2 week period, particularly at 7 to 10 days following the administration of aprepitant/ fosaprepitant				
Combined oral contraceptive	Reduced contraceptive efficacy due to increased clearance. *Note interaction only applicable to aprepitant/ fosaprepitant	Alternative non-hormonal methods should be used during and for 1 month after stopping aprepitant/ fosaprepitant				
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of NK-1 antagonist possible due to increased clearance	Avoid combination or monitor for decreased antiemetic effect. Consider using an alternative antiemetic regimen				
CYP3A4 inhibitors (e.g. azole antifungals, clarithromycin, erythromycin, grapefruit juice, ritonavir etc.)	Increased toxicity of NK-1 antagonist possible due to reduced clearance	Avoid combination or monitor for increased adverse effects of NK-1 antagonist (e.g. headache, hiccups, constipation)				
Drugs metabolised by CYP3A4 (e.g. etoposide, imatinib, irinotecan, midazolam, paclitaxel, vinblastine, vincristine etc.)	Increased effects/toxicity of these drugs possible due to inhibition of CYP3A4 by NK-1 antagonist	Avoid combination or monitor for increased toxicity especially with orally administered drugs				

General		
	Interaction	Clinical management
Warfarin	Anti-cancer drugs may alter the anticoagulant effect of warfarin.	Monitor INR regularly and adjust warfarin dosage as appropriate; consider alternative anticoagulant.
Direct oral anticoagulants (DOACs) e.g. apixaban, rivaroxaban, dabigatran	Interaction with both CYP3A4 and P-gp inhibitors /inducers. DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).	Apixaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. If treating VTE, avoid use with strong CYP3A4 and P-gp inducers. Rivaroxaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. Dabigatran: avoid combination with strong P-gp inducers and inhibitors. If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.
Digoxin	Anti-cancer drugs can damage the lining of the intestine; affecting the absorption of digoxin.	Monitor digoxin serum levels; adjust digoxin dosage as appropriate.
Antiepileptics	Both altered antiepileptic and anti- cancer drug levels may occur, possibly leading to loss of efficacy or toxicity.	Where concurrent use of an enzyme- inducing antiepileptic cannot be avoided, monitor antiepileptic serum levels for toxicity, as well as seizure frequency for efficacy; adjust dosage as appropriate. Also monitor closely for efficacy of the anti-cancer therapy.
Antiplatelet agents and NSAIDs	Increased risk of bleeding due to treatment related thrombocytopenia.	Avoid or minimise combination. If combination deemed essential, (e.g. low dose aspirin for ischaemic heart disease) monitor for signs of bleeding.
Serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs e.g. paroxetine) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. venlafaxine)	Increased risk of serotonin syndrome with concurrent use of 5-HT3 receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	Avoid combination. If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia). For more information link to TGA Medicines Safety Update
Vaccines	Diminished response to vaccines and increased risk of infection with live vaccines.	Live vaccines (e.g. BCG, MMR, zoster and varicella) are contraindicated in patients on immunosuppressive therapy. Use with caution in patients on non- immunosuppressive therapy. For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the Australian Immunisation Handbook

Administration

eviQ provides safe and effective instructions on how to administer cancer treatments. However, eviQ does not provide every treatment delivery option, and is unable to provide a comprehensive list of cancer treatment agents and their required IV line giving set/filter. There may be alternative methods of treatment administration, and alternative supportive treatments that are also appropriate. Please refer to the individual

Day 1

Approximate treatment time: 5 hours

Safe handling and waste management

Safe administration

General patient assessment prior to each day of treatment.

Peripheral neuropathy assessment tool

Any toxicity grade 2 or greater may require dose reduction, delay or omission of treatment and review by medical officer before commencing treatment.

Prime IV line(s).

Insert IV cannula or access TIVAD or CVAD.

Pre treatment medication

Verify antiemetics taken or administer as prescribed.

Verify dexamethasone taken or administer as prescribed.

O Chemotherapy - Time out

Cisplatin

Commence prehydration for cisplatin:

- administer 10 mmol magnesium sulphate (MgSO₄) in 1000 mL sodium chloride 0.9% over 60 minutes
- followed by 200 mL of mannitol 20% over 15 minutes
 mannitol should be administered via a controlled infusion
- mannitol 10% may be used as per institutional policy; there is much variation in the use of mannitol and although there is no
 conclusive evidence that mannitol should be used, many sites have used it routinely without renal toxicity. The routine use of
 frusemide to increase urine flow is not recommended. Refer to your institutional guidelines and medical orders.
- ensure patient has passed urine prior to cisplatin administration as per institutional policy.

Administer cisplatin (irritant):

- via IV infusion over 60 minutes
- flush with 100 mL of sodium chloride 0.9%.

Post hydration:

• 1000 mL sodium chloride 0.9% over 60 minutes.

Etoposide

Administer etoposide (irritant):

- via IV infusion over 30 to 60 minutes
- rapid infusion may cause hypotension
- · observe for hypersensitivity
- flush with ~ 100 mL sodium chloride 0.9%
- if using etoposide phosphate administer in ~ 50 mL sodium chloride 0.9% or glucose 5% over ~15 minutes.

Stop infusion at first sign of reaction:

- if symptoms are mild and resolve when infusion is stopped, consider recommencing infusion after review by medical officer at a slower rate.
- for severe reactions seek medical assistance immediately and do not restart infusion.

Remove IV cannula and/or deaccess TIVAD or CVAD.

Day 2 and 3

Approximate treatment time: 90 minutes

Safe handling and waste management

Safe administration

General patient assessment prior to each day of treatment.

Any toxicity grade 2 or greater may require dose reduction, delay or omission of treatment and review by medical officer before commencing treatment.

Prime IV line(s).

Insert IV cannula or access TIVAD or CVAD.

Pre treatment medication

Verify dexamethasone taken or administer as prescribed.

O Chemotherapy - Time out

Etoposide

Administer etoposide (irritant):

- via IV infusion over 30 to 60 minutes
- rapid infusion may cause hypotension
- · observe for hypersensitivity
- flush with ~ 100 mL sodium chloride 0.9%
- if using etoposide phosphate administer in ~ 50 mL sodium chloride 0.9% or glucose 5% over ~15 minutes.

Stop infusion at first sign of reaction:

- if symptoms are mild and resolve when infusion is stopped, consider recommencing infusion after review by medical officer at a slower rate.
- for severe reactions seek medical assistance immediately and do not restart infusion.

Remove IV cannula and/or deaccess TIVAD or CVAD.

Continue safe handling precautions until 7 days after completion of drug(s)

Discharge information

Antiemetics

Antiemetics as prescribed.

Patient information

· Ensure patient receives patient information sheet.

Side effects

The side effects listed below are not a complete list of all possible side effects for this treatment. Side effects are categorised into the approximate onset of presentation and should only be used as a guide.

Immediate (onset hours to day	/s)
Hypersensitivity reaction	Anaphylaxis and infusion related reactions can occur with this treatment.
	Read more about hypersensitivity reaction
Nausea and vomiting	Read more about prevention of treatment induced nausea and vomiting
Taste and smell alteration	Read more about taste and smell changes
Early (onset days to weeks)	
Oral mucositis	Erythematous and ulcerative lesions of the gastrointestinal tract (GIT). It commonly develops following chemotherapy, radiation therapy to the head, neck or oesophagus, and high dose chemotherapy followed by a blood and marrow transplant (BMT). Read more about oral mucositis
Neutropenia	Abnormally low levels of neutrophils in the blood. This increases the risk of infection. Any fever or suspicion of infection should be investigated immediately and managed aggressively. Read more about immediate management of neutropenic fever
Thrombocytopenia	A reduction in the normal levels of functional platelets, increasing the risk of abnormal bleeding. Read more about thrombocytopenia
Fatigue	Read more about fatigue
Peripheral neuropathy	Typically symmetrical sensory neuropathy, affecting the fingers and toes, sometimes progressing to the hands and feet. It is associated with several classes of anti-cancer drugs. These include taxanes, platinum-based compounds, vinca alkaloids and some drugs used to treat multiple myeloma. Read more about peripheral neuropathy
Anorexia	Loss of appetite accompanied by decreased food intake. Read more about anorexia
Ototoxicity	Tinnitus and hearing loss may occur due to damage in the inner ear. Tinnitus is usually reversible, while hearing loss is generally irreversible. Hearing loss is dose-related, cumulative and may be worse in those with pre-existing hearing problems. Read more about ototoxicity - tinnitus and hearing loss
Hypomagnesaemia, hypokalaemia, hypocalcaemia	Abnormally low levels of magnesium, potassium and calcium in the blood.
Nephrotoxicity	Renal dysfunction resulting from damage to the glomeruli, tubules or renal vasculature.
Late (onset weeks to months)	
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood.
	Read more about anaemia
Alopecia	Hair loss may occur from all parts of the body. Patients can also experience mild to moderate discomfort of the hair follicles, and rarely pain as the hair is falling out. Read more about alopecia and scalp cooling

Evidence

A search of the literature did not find strong evidence to support the use of cisplatin or any regime in the neoadjuvant treatment of small cell bladder cancer. There is consensus from the various literature that neoadjuvant chemotherapy, if tolerated by the patient should provide the best outcome. The expert reference panel supported publication of the protocol on the basis of the information summarised below, the committee was most strongly influenced by Siefeker- Radkte et al¹, Bex et al² and Meijer et al.³

This protocol has been used extensively in the treatment of small cell lung cancer.

Source	Study & Year Published	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
Phase II trials	Siefker-Radtke et al 2009 ¹	Yes	No	cisplatin 20mg/m ² etoposide 80mg/m ² d 1-5; alternating with ifosfamide, doxorubicin
Case Studies	-	N/A	-	-
Observational studies	Meijer et al 2013 ³	Yes	Yes	-
	Lynch et al 2013 ⁴	Yes	n/a	various regimens used
	Bex et al 2005 ²	Yes	Yes	-
	Siefker-Radtke et al 2004 ⁵	Yes	n/a	various regimens used
	Lohrisch et al 1999 ⁶	Yes	n/a	-
	Choong et al 2005 ⁷	Yes	n/a	not specified
	Mukesh et al 2008 ⁸	Yes	n/a	doses not specified
	Quek et al 2005 ⁹	Yes	No	cisplatin/etoposide/doxorubicin
	Asmis et al 2004 ¹⁰	Yes	n/a	either carboplatin/etoposide or EP doses not specified
Guidelines	Date published/revised	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
NCCN	v.1 2012	Yes	no doses	refers to small cell lung cancer
BCCA	April 2013	Yes	Yes	
ссо	-	N/A	-	

Efficacy

Author/Year	No. of patients	Treatment	Overall survival	Response Rate	Cancer specific free survival	5 y sur
Meijer 2013 ³	27	MVAC, IEP, EP, Cyclophosphamide/doxorubicin/etoposide, or carboplatin/etoposide followed by EBRT	24 months (5 year OS 22.2%)	-	complete responders- 52 months; incomplete responders- 22 months	45
Lynch 2013 ⁴	48 (36 pt with <pt2n0m0)< td=""><td>IA/EP (54%), EP (15%), MVAC (10%) followed by surgery, RT or chemoradiation</td><td>187 months (95% CI 160 to infinity)</td><td>-</td><td>-</td><td></td></pt2n0m0)<>	IA/EP (54%), EP (15%), MVAC (10%) followed by surgery, RT or chemoradiation	187 months (95% CI 160 to infinity)	-	-	
Siefker-Radtke 2009 (prospective) ¹	18	IA/EP plus cystectomy	58 months (CI 58 months to not achieved)	78%	-	
Siefker-Radtke 2004 (retrospective) ⁵	46	Upfront cystectomy -v- preoperative chemotherapy including EP, IA, methotrexate/cisplatin	36-v-78% (cystectomy alone -v- neoadjuvant chemotherapy)	-	-	
Bex 2005 ²	17	TUR+platinum-based chemotherapy and local RT (56-70Gy).	12 months (range 4	-	-	

Author/Year	No. of patients	Treatment	Overall survival	Response Rate	Cancer specific free survival	s
			months to 84 months)			
Lohrisch 1999 ⁶	10	EP followed by local RT	2 year 70%	-	-	4.
Choong 2005 ⁷	3	1 patient had neoadjuvant, 2 adjuvant chemotherapy (not specified- most likely EP)	2 patients alive at the end of the study. OS of other not known	-	-	
Mukesh 2008 ⁸	6/11 had chemotherapy for limited disease	3 carboplatin/etoposide pre cystectomy and RT (1 pt died after chemotherapy), 2 CAV, 1 ACE	33 months (range 6-60 months). 3 alive at time of article publication	-	-	
Quek 2005 ⁹	20/25 small cell bladder	14 chemotherapy (13 adjuvant 1 preoperative). cisplatin/etoposide/doxorubicin	30% - 2 years 10% - 5 years	-	-	
Asmis 2004 ¹⁰	8/12 limited bladder cancer	1 neoadjuvant cisplatin etoposide, rest sequential chemotherapy and radiation therapy with either carboplatin/etoposide or EP	19.8 months, 5 alive at 31.2 months	-	-	

This table had been expanded from Macedo et al 2011¹¹

IA= ifosfamide & doxorubicin; EP= etoposide & cisplatin; MVAC= methotrexate, vinblastine, doxorubicin & cisplatin; IEP= ifosfamide, etoposide & cisplatin; CAV= cyclophosphamide, doxorubicin & vincristine; ACE= doxorubicin, cyclophosphamide & etoposide

Toxicity

Based on the meta-analysis of the cisplatin-based regimens compared with carboplatin-based regimens in small cell lung cancer, statistically significantly more haematological toxicities (anaemia, thrombocytopenia, leucopenia) were observed in patients treated with carboplatin. Other toxicities (nausea, neurotoxicity, nephrotoxicity) were significantly more common in patients treated with cisplatin.¹²

	Patients With	s Any Grade				Severe Toxicity (grade ≥ 3)							
Toxicity	With Toxicity Information	Cisplatin (%)	Carboplatin (%)	Exact OR	95% CI	P**	<i>P</i> † for Homogeneity		Carboplatin (%)	Exact OR	95% CI	P*	Pt for Homogeneity
Leucopenia	655	74	77	1.22	0.81 to 1.88	.357	<.001	34	34	0.96	0.67 to 1.37	.863	< .001
Neutropenia	458	86	90	1.53	0.81 to 2.92	.177	. 397	64	73	1.74	1.07 to 2.83	.021	.999
Anemia	512	84	89	1.72	0.99 to 3.03	.049	.046	16	25	1.73	1.12 to 2.89	.011	< .001
Platelets	512	39	71	3.36	2.83 to 6.34	<.001	<.001	14	42	3.78	2.86 to 7.19	<.001	< .001
Nausea/vomiting	655	72	63	0.66	0.47 to 0.93	.013	.012	6	3	0.49	0.21 to 1.11	.066	.999
Stomatitis	655	25	21	0.78	0.52 to 1.17	.239	.065	1	< 1	0.24	0.01 to 3.32	.320	.999
Diarrhea	458	19	22	1.23	0.76 to 2.00	.415	.999	2	2	0.99	0.18 to 5.40	.999	.999
Constipation	239	39	51	1.58	0.92 to 2.73	.091	.999	3	5	1.51	0.35 to 7.48	.749	.999
Neurotoxicity	416	19	7	0.29	0.14 to 0.58	<.001	. 243	1	<1	0.35	0.01 to 7.27	.569	.999
Renal toxicity	415	25	10	0.34	0.19 to 0.61	<.001	.787	1.5	5	0.28	0.01 to 3.78	.351	.540
Taxic deaths	655		_	—			_	1.9	1.5	0.80	0.19 to 3.18	.769	.101

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References

- Siefker-Radtke, A. O., A. M. Kamat, H. B. Grossman, et al. 2009. "Phase II clinical trial of neoadjuvant alternating doublet chemotherapy with ifosfamide/doxorubicin and etoposide/cisplatin in small-cell urothelial cancer." J Clin Oncol 27(16):2592-2597.
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History

Version 5

Date	Summary of changes
10/09/2020	Patient information title updated- 'small cell' added. Version number changed to V.5.

Version 4

Date	Summary of changes
04/05/2020	Treatment schedule cycle title changed to 'cycle 1 to 4'. Patient information updated to include 'You will have 4 to 6 cycles'. Day 1 approximate treatment time changed to 5 hours. Version number changed to V.4.
30/06/2020	Protocol reviewed electronically by Medical Oncology Reference Committee. No changes. Review 5 years.

Version 3

Date	Summary of changes
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27/03/2015	New protocol discussed at Medical Oncology Reference Committee meeting
11/05/2015	Approved and published on eviQ. Review 2 years.
31/03/2017	Protocol discussed and decided to have a 5 year review period. Next due for review in 2020.
31/05/2017	Transferred to new eviQ website. Version number changed to V.2.
	Antiemetic change: Netupitant/palonosetron combination has replaced aprepitant and a $5HT_3$ receptor antagonist in combination with dexamethasone for all highly emetogenic regimens.
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.3.

The information contained in this protocol is based on the highest level of available evidence and consensus of the eviQ reference committee regarding their views of currently accepted approaches to treatment. Any clinician (medical oncologist, haematologist, radiation oncologist, medical physicist, radiation therapist, pharmacist or nurse) seeking to apply or consult this protocol is expected to use independent clinical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use is subject to eviQ's disclaimer available at www.eviQ.org.au

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Patient information - Bladder/urinary tract small cell cancer - Cisplatin and etoposide

Patient's name:

Your treatment

The treatment schedule below explains how the drugs for this treatment are given.

Cisplatin and etoposide This treatment cycle is repeated every 21 days. You will have 4 to 6 cycles. Your doctor will advise you of the number of treatments you will have. Day Treatment How it is given How long it takes 1 Cisplatin By a drip into a vein About 5 hours (siss-PLAT-in) Etoposide (e-TOE-poe-side) 2 and 3 Etoposide About 1.5 hours By a drip into a vein

When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you become unwell.

0	IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you have any of the following at any time:	Emergency contact details Ask your doctor or nurse from your treating team who to contact if you have a problem
 chills, shortn uncon pain, ti 	perature of 38°C or higher sweats, shivers or shakes less of breath trolled vomiting or diarrhoea ingling or discomfort in your chest or arms ecome unwell.	Daytime: Night/weekend: Other instructions:

During your treatment immediately tell the doctor or nurse looking after you if you get any of the following problems:

- · leaking from the area where the drugs are being given
- pain, stinging, swelling or redness in the area where the drugs are being given or at any injection sites
- a skin rash, itching, feeling short of breath, wheezing, fever, shivers, or feeling dizzy or unwell in any way (allergic reaction).

Other information about your treatment

Changes to your dose or treatment delays

Sometimes a treatment may be started at a lower dose or the dose needs to be changed during treatment. There may also be times when your treatment is delayed. This can happen if your doctor thinks you are likely to have severe side effects, if you get severe side effects, if your blood counts are affected and causing delays in treatment, or if you are finding it hard to cope with the treatment. This is called a dose reduction, dose change or treatment delay. Your doctor will explain if you need any changes or delays to your treatment and the reason why.

Blood tests and monitoring

Anti-cancer drugs can reduce the number of blood cells in your body. You will need to have regular blood tests to check that your blood cell count has returned to normal. If your blood count is low, your treatment may be delayed until it has returned to normal. Your doctor or nurse will tell you when to have these blood tests.

Other medications given during this treatment

• Anti-sickness (anti-nausea) medication: you may be given some anti-sickness medication. Make sure you take this medication as your doctor or nurse tells you, even if you don't feel sick. This can help to prevent the sickness starting.

Side effects

Cancer treatments can cause damage to normal cells in your body, which can cause side effects. Everyone gets different side effects, and some people will have more problems than others.

The table below shows some of the side effects you may get with this treatment. You are unlikely to get all of those listed and you may also get some side effects that have not been listed.

Tell your doctor or nurse about any side effects that worry you. Follow the instructions below and those given to you by your doctor or nurse.

Allergic reaction	Allergic reactions are uncommon but can be life threatening.
Allergic reaction	 If you feel unwell during the infusion or shortly after it, or:
	 get a fever, shivers or shakes
	 o feel dizzy, faint, confused or anxious
	 start wheezing or have difficulty breathing
	 have a rash, itch or redness of the face
	While you are in hospital: Tell your doctor or nurse immediately.
	<u>After you leave:</u> Contact your doctor or nurse immediately, or go to the nearest hospital Emergency Department.
Vausea and vomiting	You may feel sick (nausea) or be sick (vomit).
•	• Take your anti-sickness medication as directed even if you don't feel sick.
	 Drink plenty of fluids (unless you are fluid restricted).
	Eat small meals more frequently.
	Try food that does not require much preparation.
	Try bland foods like dry biscuits or toast.
	Gentle exercise may help with nausea.
	 Ask your doctor or nurse for eviQ patient information - Nausea and vomiting during cancer treatment.
	• Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have uncontrolled vomiting or feel dizzy or light-headed.
aste and smell changes	You may find that food loses its taste or tastes different.
-	These changes are likely to go away with time.
	Do your mouth care regularly.
	Chew on sugar-free gum or eat sugar-free mints.
	Add flavour to your food with sauces and herbs.
	• Ask your doctor or nurse for eviQ patient information - Taste and smell changes during cancer treatment.
Early (onset days to weeks)	
Mouth pain and soreness	You may have:
(mucositis)	 bleeding gums
	 mouth ulcers
	 a white coating on your tongue
	◦ pain in the mouth or throat
	 difficulty eating or swallowing.
	• Avoid spicy, acidic or crunchy foods and very hot or cold food and drinks.
	Try bland and soft foods.
	• Brush your teeth gently with a soft toothbrush after each meal and at bedtime. If you normally floss continue to do so.
	 Rinse your mouth after you eat and brush your teeth, using either: 1/4 teaspoon of salt in 1 cup of warm water, or
	 1/4 teaspoon of bicarbonate of soda in 1 cup of warm water
	 Ask your doctor or nurse for eviQ patient information - Mouth problems during cancer treatment.
	 Tell your doctor or nurse if you get any of the symptoms listed above.

Infection risk (neutropenia)	 This treatment lowers the amount of white blood cells in your body. The type of white blood cells that help to fight infection are called neutrophils. Having low level of neutrophils is called neutropenia. If you have neutropenia, you are at greater risk of getting an infection. It also means that your body can't fight infections as well as usual. This is a serious side effect, and can be life threatening. Wash your hands often. Keep a thermometer at home and take your temperature regularly, and if you feel unwell. Do your mouth care regularly. Inspect your central line site (if you have one) daily for any redness, pus or swelling. Limit contact with people who are sick. Learn how to recognise the signs of infection. Ask your doctor or nurse for eviQ patient information - Infection during cancer treatment. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms: a temperature of 38°C or higher chills, shivers, sweats or shakes a sore throat or cough uncontrolled diarrhoea shortness of breath a fast heartbeat become unwell even without a temperature.
Low platelets (thrombocytopenia)	 This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising. Try not to bruise or cut yourself. Avoid contact sport or vigorous exercise. Clear your nose by blowing gently. Avoid constipation. Brush your teeth with a soft toothbrush. Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to. Tell your doctor or nurse if you have any bruising or bleeding. Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.
Tiredness and lack of energy (fatigue)	 You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or things you enjoy. Do not drive or operate machinery if you are feeling tired. Nap for short periods (only 1 hour at a time) Prioritise your tasks to ensure the best use of your energy. Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted). Try some gentle exercise daily. Allow your friends and family to help. Tell your doctor or nurse if you get any of the symptoms listed above.
Nerve damage (peripheral neuropathy)	 You may notice a change in the sensations in your hands and feet, including: tingling or pins and needles numbness or loss of feeling pain. You may find it difficult to do everyday activities, such as doing up buttons or picking up small objects. Test water temperature with your elbow when bathing to avoid burns. Use rubber gloves, pot holders and oven mitts in the kitchen. Wear rubber shoes or boots when working in the garden or garage. Keep rooms well lit and uncluttered. Ask your doctor or nurse for eviQ patient information - Nerve problems during cancer treatment. Tell your doctor or nurse if you get any of the symptoms listed above.

Appetite loss (anorexia)	You may not feel like eating.
	Try to avoid drinking fluids at meal times.
	Try to eat small meals or snacks regularly throughout the day.
	• Try to eat food that is high in protein and calories.
	• If you are worried about how much food you can eat, or if you are losing weight, ask to speak to a dietitian.
Hearing changes	You may get ringing in your ears or loss of hearing.
(ototoxicity)	You may have your hearing tested before and during your treatment.
	• Tell your doctor or nurse as soon as possible if you notice any changes to your hearing.
Low blood magnesium,	This may be found from your routine blood tests and treated by your doctor.
potassium and calcium	If it is severe you may get:
levels (hypomagnesaemia,	 muscle cramps or twitches
hypokalaemia,	 numbness or tingling in your fingers, toes or around your mouth
hypocalcaemia)	 constipation
	◊ an irregular heartbeat
	 sleepy, drowsy or confused
	 Tell your doctor or nurse as soon as possible if you get any of the signs or symptoms listed above.
Kidney damage	This treatment can cause changes to how your kidneys work.
	You will have blood tests to make sure your kidneys are working properly.
	• You may need to drink more fluids while you are having treatment. Your doctor or nurse will tell you if you need to do this.
	• Tell your doctor or nurse as soon as possible if you notice that your urine changes colour or you don't need to empty your bladder as often.
Late (onset weeks to months)	
Low red blood cells	You may feel dizzy, light-headed, tired and appear more pale than usual.
(anaemia)	• Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion.
	• Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.
Hair loss (alopecia)	Your hair may start to fall out from your head and body.
	Hair loss usually starts 2 to 3 weeks after your first treatment.
	You may become completely bald and your scalp might feel tender.
	- Use a gentle shamped and a soft brush

- Use a gentle shampoo and a soft brush.
- Take care with hair products like hairspray, hair dye, bleaches and perms.
- Protect your scalp from the cold with a hat, scarf or wig.
- Protect your scalp from the sun with a hat or sunscreen of SPF 50 or higher.
- Moisturise your scalp to prevent itching.
- Ask your doctor or nurse about the Look Good Feel Better program

General advice for people having cancer treatment

Chemotherapy safety

- Learn how to keep you and your family safe while you are having anticancer drugs.
- See our patient information sheet Chemotherapy safety at home.

Blood clot risk

- Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).
- Tell your doctor if you have a family history of blood clots.
- A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.

• If you have any of these symptoms go to your nearest hospital Emergency Department.

Medications and vaccinations

- Before you start treatment, tell your doctor about any medications you are taking, including vitamins or herbal supplements.
- Don't stop or start any medications during treatment without talking to your doctor and pharmacist first.
- Paracetamol is safe to take if you have a headache or other mild aches and pains. It is recommended that you avoid taking aspirin, ibuprofen and other anti-inflammatory type medications for pain while you are having treatment. However, if these medications have been prescribed by your doctor, do not stop taking them without speaking with your doctor.
- Vaccinations such as flu and tetanus vaccines are safe to receive while having treatment. Do not have any live vaccines during your treatment or for 6 months after it finishes. If you are unsure, check with your doctor before you have any vaccinations.
- People you live with should be fully vaccinated, including having live vaccines according to the current vaccination schedule. Extra care needs to be taken with hand washing and careful disposal of soiled nappies for infants who have recently received the rotavirus vaccine.

Other medical and dental treatment

- If you go to hospital or any other medical appointment (including dental appointments), always tell the person treating you that you are receiving anticancer drugs.
- Before you have any dental treatment, talk to your doctor.

Diet

- While you are receiving this treatment it is important that you try to maintain a healthy diet.
- Grapefruit and grapefruit juice can interact with your medication and should be avoided while you are on this treatment.
- Speak to your doctor or nurse about whether drinking alcohol is safe with your treatment.
- If you have any concerns about recent weight loss or weight gain or questions about your diet, ask to speak to a dietitian.

Fertility

- Some cancer treatments can reduce your fertility. This can make it difficult or impossible to get pregnant or father a child.
- Talk to your doctor or nurse before you start any treatment. Depending on your situation there may be fertility sparing options available to you and/or your partner, discuss these with your doctor or nurse.

Pregnancy and breastfeeding

- Some cancer treatments can be dangerous to unborn babies. Talk to your doctor or nurse if you think there is any chance that you could be pregnant.
- Do not try to get pregnant or father a child during this treatment. Contraception should be used during treatment and after stopping treatment. Ask your doctor or nurse about what type of contraception you should use.
- If you are planning pregnancy/fatherhood after completing this treatment, talk to your doctor. Some doctors advise waiting between 6 months and 2 years after treatment.
- Do not breastfeed if you are on this treatment, as anti-cancer medications can also pass into breast milk.

Sex life and sexuality

- The desire to have sex may decrease as a result of this treatment or its side effects.
- Your emotions and the way you feel about yourself may also be affected by this treatment.
- It may help to discuss your concerns with your partner and doctor or nurse.

Risk of developing a second cancer

• Some anticancer treatments can increase your chance of developing a second cancer, this is rare. Your doctor will discuss with you the specific risks of your treatment.

Quitting smoking

- It is never too late to quit smoking. Quitting smoking is one of the best things you can do to help your treatment work better.
- There are many effective tools to improve your chances of quitting.
- Talk to your treating team for more information and referral to a smoking cessation support service.

Staying active

- Research shows that exercise, no matter how small, has many benefits for people during and after cancer treatment.
- Talk to your doctor before starting an exercise program. Your doctor can advise whether you need a modified exercise program.

For more information about cancer treatment, side effects and side effect management see our Patient and carers section.

Telephone support

• Call Cancer Council on 13 11 20 for cancer information and support

Bladder and urinary tract cancer information

- Australian Government Bladder and Bowel bladderbowel.gov.au
- Australian Government Department of Health & Ageing Stoma appliance scheme health.gov.au/internet/main/publishing.nsf/Content/Stoma+Appliance+Scheme-1
- BEAT Bladder Cancer Australia Inc. beatbladdercanceraustralia.org.au/
- Continence Foundation of Australia continence.org.au
- National Continence Program health.gov.au/initiatives-and-programs/national-continence-program-ncp
- National Public Toilet map toiletmap.gov.au
- Recovering after Pelvic Radiation Therapy: A guide for women Recovering after Pelvic Radiation Therapy: A guide for women

General cancer information and support

- Australian Rare Cancer (ARC) Portal arcportal.org.au/
- Beyondblue beyondblue.org.au
- Cancer Australia canceraustralia.gov.au
- Cancer Council Australia cancer.org.au
- Cancer Voices Australia cancervoicesaustralia.org
- CanTeen canteen.org.au
- Carers Australia carersaustralia.com.au
- CHILL Cancer related hair loss scalpcooling.org
- eviQ Cancer Treatments Online eviq.org.au
- LGBTQI+ People and Cancer cancercouncil.com.au/cancer-information/lgbtqi
- Look Good Feel Better lgfb.org.au
- Patient Information patients.cancer.nsw.gov.au
- Radiation Oncology Targeting Cancer targetingcancer.com.au
- Redkite redkite.org.au
- Return Unwanted Medicines returnmed.com.au
- Staying active during cancer treatment patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active

Quit smoking information and support

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information and support to help you quit smoking. Talk to your treating team about any other questions you may have.

- Call Quitline on 13 QUIT (13 78 48)
- iCanQuit iCanQuit.com.au
- Patient Information patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking
- Quitnow quitnow.gov.au

Additional notes:

This document is a guide only and cannot cover every possible situation. The health professionals caring for you should always consider your individual situation when making decisions about your care. Contact your cancer clinic staff or doctor if you have any questions or concerns about your treatment, or you are having problems coping with side effects. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use of this document is subject to eviQ's disclaimer available at www.eviQ.org.au

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