

Non small cell lung cancer locally advanced or metastatic cARBOplatin and DOCEtaxel

ID: 226 v.6 Endorsed Essential Medicine List

⚠ ADDIKD Carboplatin dosing:

For dosing carboplatin, ADDIKD recommends that:

- Directly measured glomerular filtration rate (mGFR) is the preferred kidney function value in the Calvert formula, especially where estimated kidney function may be unreliable for accurate therapeutic dosing.
- Where mGFR is unavailable, eGFR adjusted to an individual's body surface area (BSA-adjusted eGFR) is a suitable alternative for use in the Calvert formula.
- Kidney function should not be capped at 125 mL/min for use in the Calvert formula.
- Recalculation of carboplatin doses at each cycle is unnecessary, except when baseline kidney function (e.g., eGFR) alters by > 20% or when there is a change in the clinical status of the patient.

For further information refer to the [eviQ Factsheet](#) around carboplatin dosing and the carboplatin drug monograph within the ADDIKD guideline. To assist with calculations, use the eviQ [Estimated Glomerular Filtration Rate \(eGFR\)](#) and [carboplatin dose calculators](#).

Check for clinical trials in this patient group. Link to [Australian Clinical Trials](#) website

Link to [Clinical practice guidelines for the treatment of lung cancer](#)

The anticancer drug(s) in this protocol may 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 [eviQ Estimated Glomerular Filtration Rate \(eGFR\) calculator](#).

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

2022

[Click here](#)



Treatment schedule - Overview

Cycle 1 to 4

Drug	Dose	Route	Day
DOCEtaxel	75 mg/m ²	IV infusion	1
cARBOplatin	5 AUC *	IV infusion	1

*if estimated GFR is >125 mL/min (i.e. 5 AUC dose >750 mg), obtaining direct measurement rather than an estimated renal function and/or dose capping is strongly recommended.

Frequency: 21 days

Cycles: 4 unless otherwise indicated

Notes:

The original protocol used AUC 6 however AUC 5 is considered a reasonable starting dose in this patient population.

Consider combination immunotherapy chemotherapy regimens in patients with ECOG 0-1 and no contraindications.

Drug status: All drugs in this protocol are on the [PBS general schedule](#)

Cost: ~ \$160 per cycle

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 before chemotherapy		
Dexamethasone	8 mg (PO)	TWICE a day with or after food
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	8 mg (PO)	60 minutes before chemotherapy
DOCEtaxel	75 mg/m ² (IV infusion)	in 250 mL to 500 mL sodium chloride 0.9% over 60 minutes
cARBOplatin	5 AUC (IV infusion)	in 500 mL glucose 5% over 30 to 60 minutes (if estimated GFR is 125 mL/min (i.e. AUC 5 dose > 750 mg), obtaining direct measurement rather than an estimated renal function and/or dose capping is strongly recommended)
Day 2 and 3		
Dexamethasone	8 mg (PO)	ONCE a day (or in divided doses) with or after food. Note: dexamethasone dose on day 3 may not be required and may be reduced or omitted at the clinicians discretion *

* Link to [ID 7 Prevention of antineoplastic induced nausea and vomiting](#)

Frequency: 21 days

Cycles: 4 unless otherwise indicated

Indications and patient population

- Locally advanced, recurrent or metastatic non small cell lung cancer

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
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Hypersensitivity/infusion related reaction	<p>High risk with docetaxel.</p> <p>High risk with carboplatin. Hypersensitivity risk increases with number of cycles of carboplatin. Rechallenge with carboplatin after hypersensitivity carries a high risk of anaphylaxis, and where clinically indicated, should be undertaken with a desensitisation protocol with appropriate supports in place. Refer to local institutional policy.</p> <p>Read more about Hypersensitivity reaction</p>
Premedication	<p>The product information states that premedication is required for this treatment. Please refer to the treatment schedule for the suggested premedication regimen. This may be substituted to reflect institutional policy.</p> <p>Read more about premedication for prophylaxis of taxane hypersensitivity reactions</p>
Emetogenicity MODERATE	<p>Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy.</p> <p>Carboplatin AUC ≥ 4 is classified by MASCC/ESMO Antiemetic Guidelines 2016 and ASCO Antiemetic Guidelines 2017 as having moderate emetogenicity.</p> <p>However, a NK1 receptor antagonist and a 5HT₃ receptor antagonist in combination with dexamethasone are available on the PBS for primary prophylaxis of carboplatin induced nausea and vomiting.</p> <p>Note: a steroid has been included both as an antiemetic and premedication for hypersensitivity in this protocol.</p> <p>Ensure that patients also have sufficient antiemetics for breakthrough emesis:</p> <p>Metoclopramide 10 mg three times a day when necessary (maximum of 30 mg/24 hours, up to 5 days) OR</p> <p>Prochlorperazine 10 mg PO every 6 hours when necessary.</p> <p>Read more about preventing anti-cancer therapy induced nausea and vomiting</p>
Peripheral neuropathy	<p>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.</p> <p>Read more about peripheral neuropathy</p> <p>Link to chemotherapy-induced peripheral neuropathy screening tool</p>
Blood tests	<p>FBC, EUC, eGFR, and LFTs at baseline and prior to each cycle. Calcium and magnesium at baseline and as clinically indicated. Recalculation of carboplatin doses at each cycle is unnecessary, except when baseline kidney function (e.g., eGFR) alters by greater than 20% or when there is a change in the clinical status of the patient.</p>
Hepatitis B screening and prophylaxis	<p>Routine screening for HBsAg and anti-HBc is NOT usually recommended for patients receiving this treatment.</p> <p>Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy</p>
Vaccinations	<p>Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.</p> <p>Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook.</p> <p>Read more about COVID-19 vaccines and cancer.</p>
Fertility, pregnancy and lactation	<p>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.</p> <p>Read more about the effect of cancer treatment on fertility</p>

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 \(ADIKD\)](#).

For dosing carboplatin, ADDIKD recommends that:

- Directly measured glomerular filtration rate (mGFR) is the preferred kidney function value in the Calvert formula, especially where estimated kidney function may be unreliable for accurate therapeutic dosing.
- Where mGFR is unavailable, eGFR adjusted to an individual's body surface area (BSA-adjusted eGFR) is a suitable alternative for use in the Calvert formula.
- Kidney function should not be capped at 125 mL/min for use in the Calvert formula.
- Recalculation of carboplatin doses at each cycle is unnecessary, except when baseline kidney function (e.g., eGFR) alters by > 20% or when there is a change in the clinical status of the patient.

For further information refer the [eviQ Factsheet](#) around carboplatin dosing and the carboplatin drug monograph within the ADDIKD guideline. To assist with calculations, use the eviQ [Estimated Glomerular Filtration Rate \(eGFR\)](#) and [carboplatin dose calculators](#).

Note: All dose reductions are calculated as a percentage of the starting dose

Haematological toxicity	
ANC x 10 ⁹ /L (pre-treatment blood test)	
1.0 to less than 1.5	Refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if patient is clinically well.
0.5 to less than 1.0	Delay treatment until recovery
less than 0.5	Delay treatment until recovery and reduce docetaxel and carboplatin by 25% for subsequent cycles
Febrile neutropenia	Delay treatment until recovery and reduce docetaxel and carboplatin by 25% for subsequent cycles
Platelets x 10 ⁹ /L (pre-treatment blood test)	
75 to less than 100	The general recommendation is to delay, however if the patient is clinically well it may be appropriate to continue treatment; refer to treating team and/or local institutional guidelines.
50 to less than 75	Delay treatment until recovery
less than 50	Delay treatment until recovery and reduce docetaxel and carboplatin by 25% for subsequent cycles
Renal impairment	
Recalculate carboplatin dose using Calvert formula	
Hepatic impairment	

Hepatic impairment	
Hepatic dysfunction	
Minimal	Reduce docetaxel by 25%
Mild	Reduce docetaxel by 50%
Moderate/Severe	Omit docetaxel

Peripheral neuropathy	
Grade 2 which is present at the start of the next cycle	Reduce docetaxel by 25%; if persistent, reduce docetaxel by 50%
Grade 3 or Grade 4	Omit docetaxel

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 docetaxel and carboplatin by 25% 3 rd occurrence: Reduce docetaxel and carboplatin by 50% 4 th occurrence: Omit docetaxel and carboplatin
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 docetaxel and carboplatin by 50% 2 nd occurrence: Omit docetaxel and carboplatin

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](#)

Carboplatin		
	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
Paclitaxel	Administration schedule may influence the development of myelosuppression	Minimise toxicity by administering paclitaxel first in regimens using the combination

Docetaxel		
	Interaction	Clinical management
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin, grapefruit juice etc.)	Increased toxicity of docetaxel possible due to reduced clearance	Avoid combination or monitor for docetaxel toxicity
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of docetaxel possible due to increased clearance	Avoid combination or monitor for decreased clinical response to docetaxel

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	<p>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.</p> <p>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.</p>
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	<p>Interaction with both CYP3A4 and P-gp inhibitors /inducers.</p> <p>DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).</p>	<p>Apixaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. If treating VTE, avoid use with strong CYP3A4 and P-gp inducers.</p> <p>Rivaroxaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors.</p> <p>Dabigatran: avoid combination with strong P-gp inducers and inhibitors.</p> <p>If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.</p>
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-HT ₃ receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	<p>Avoid combination.</p> <p>If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia).</p> <p>For more information link to TGA Medicines Safety Update</p>
Vaccines	Diminished response to vaccines and increased risk of infection with live vaccines.	<p>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.</p> <p>For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the Australian Immunisation Handbook</p>

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: 2.5 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 [taxane premedication](#) taken or administer as prescribed.

Verify antiemetics taken or administer as prescribed.

⌚ Chemotherapy - Time out

Docetaxel

Prior to administration:

- assess patient for fluid retention or weight gain prior to each cycle
 - notify medical officer of any signs of fluid retention or unexplained weight gain.

The medicines information reference publications stipulate the use of non-PVC containing bags and administration sets. However, this is not consistently recommended in the product information, therefore the decision should be at the discretion of the administering unit.

Administer docetaxel ([irritant with vesicant properties](#)):

- via IV infusion over 60 minutes
- observe for hypersensitivity reactions
- flush with ~ 100 mL of sodium chloride 0.9%.

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.

Carboplatin

Administer carboplatin ([irritant](#)):

- via IV infusion over 30 to 60 minutes
- observe for hypersensitivity reactions
- flush with ~100 mL of sodium chloride 0.9%
- hypersensitivity risk increases with number of cycles administered.

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](#).

Discharge information

Antiemetics

- Antiemetics as prescribed.

Premedication

- Premedication for next cycle of chemotherapy.

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 days)	
Hypersensitivity reaction	Anaphylaxis and infusion related reactions can occur with this treatment. Read more about hypersensitivity reaction Read more about premedication for prophylaxis of taxane hypersensitivity reactions
Nausea and vomiting	Read more about prevention of treatment induced nausea and vomiting
Headache	
Taste and smell alteration	Read more about taste and smell changes

Early (onset days to weeks)	
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
Arthralgia and myalgia	Generalised joint pain or and/or stiffness and muscle aches, often worse upon waking or after long periods of inactivity. Can improve with movement. May be mild or severe, intermittent or constant and accompanied by inflammation. Read more about arthralgia and myalgia
Diarrhoea	Read more about treatment induced diarrhoea
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
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
Palmar-plantar erythrodysaesthesia (PPE) - hand-foot syndrome (HFS)	Bilateral erythema, tenderness, pain, swelling, tingling, numbness, pruritus, dry rash, or moist desquamation and ulceration of the palms and soles. It is also known as hand-foot syndrome (HFS). Symptoms appear to be dose dependent and palms are affected more than soles. Read more about hand-foot syndrome associated with chemotherapy
Fluid retention syndrome	Fluid retention, including peripheral oedema and weight gain, may occur with docetaxel treatment. The main risk factor for development is cumulative docetaxel dose. Pre-medication with dexamethasone may be used. Fluid retention will slowly resolve after cessation of treatment. Read more about fluid retention syndrome associated with docetaxel
Ocular changes	Symptoms may include eye pain, blurred vision, blepharitis, uveitis, optic neuritis, tear duct stenosis, conjunctivitis, hyperlacrimation, watery or dry eyes and photophobia.

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
Nail changes	Hyperpigmentation, paronychia, onycholysis, splinter haemorrhage, pyogenic granuloma formation, subungal haematoma and subungal hyperkeratosis are some of the nail changes associated with anti-cancer drugs. Read more about nail toxicities

Evidence

The evidence supporting this regimen comes from a randomised phase III study by Fossella et al, investigating whether docetaxel plus platinum regimens (docetaxel/cisplatin and docetaxel/carboplatin) improve survival and quality of life in advanced NSCLC compared with vinorelbine plus cisplatin as first line chemotherapy.¹

Patients (1218) with stage IIIB to IV NSCLC were enrolled from 140 institutions in 28 countries between July 1998 and January 2000.

The median follow-up was 10 months.

Efficacy

Approximately 60% of patients in each group had stage IV disease. Patients treated with docetaxel carboplatin or docetaxel cisplatin reported consistently improved global QoL compared with patients on vinorelbine cisplatin.

The 1 year survival was 38% (HR=97.2%; p=0.657) and the 2 year survival was 18% (HR=97.2%; p=0.657).¹

TAX 326 ¹	Docetaxel Carboplatin	Vinorelbine Cisplatin	p-value
Response rate	24%	25%	0.870
Time to progression	22	23	0.805
Overall median survival	9.4 months	9.9 months	0.657

Survival:¹

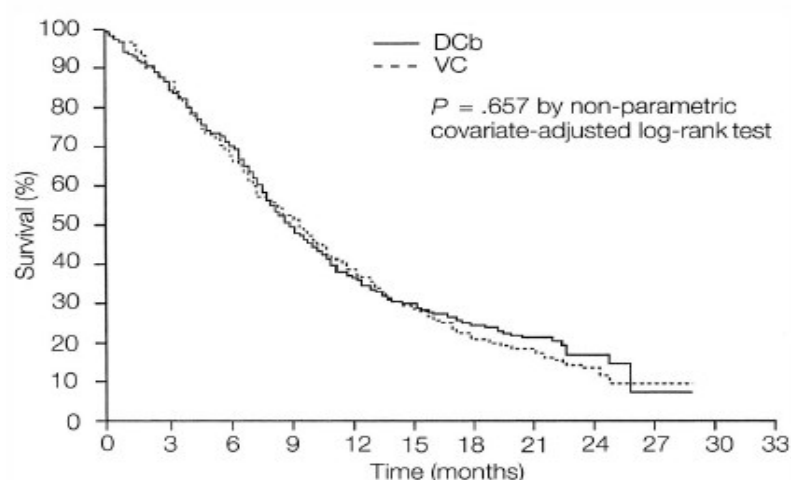


Fig 2. Nonparametric covariate-adjusted estimates of overall survival for docetaxel plus carboplatin (DCb) versus vinorelbine plus cisplatin (VC).

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TAX326 ¹	Docetaxel cisplatin n=408 (%)	Docetaxel carboplatin n=406 (%)	Vinorelbine cisplatin n=404 (%)
Overall response	32	24	25
95% CI	27 to 36	20 to 28	20 to 29
Complete response	2	1	2
Partial response	30	23	23
No change or stable disease	43	46	42
Progressive disease	18	22	21
Not assessable	8	8	12

In the planned pair-wise comparison between docetaxel/carboplatin (Dcb) versus vinorelbine/cisplatin (VC), the overall median survival was similar, 9.4 months and 9.9 months respectively. One and 2-year survival rates for Dcb versus VC were 38%v40%, and 18% v 14% respectively.

Toxicity

More patients on the vinorelbine cisplatin arm (22.5%) discontinued treatment because of adverse events compared with those on the docetaxel carboplatin (9.1%) and docetaxel cisplatin (15.7%).

Neutropenia, febrile neutropenia and thrombocytopenia were similar for all three arms, but there was a higher incidence of anaemia with cisplatin/vinorelbine arm. There were no treatment related deaths reported.

Grade 3 and 4 Toxicities from TAX 326 study group¹

Adverse event ¹	Vinorelbine Cisplatin n=396 (%)	Docetaxel Cisplatin n=406 (%)	Docetaxel Carboplatin n=401(%)
Leucopenia	55	43	50
Neutropenia	79	75	74
Thrombocytopenia	4	3	7
Anaemia	24	7	11
Infection	8	8	11
Asthenia	14	12	11
Nausea	16	10	6
Pulmonary	11	10	14
Pain	8	8	9
Vomiting	16	8	4
Diarrhoea	3	7	5
Anorexia	5	5	3

References

- 1 Fossella, F., J. R. Pereira, Pawel J. von, et al. 2003. "Randomized, multinational, phase III study of docetaxel plus platinum combinations versus vinorelbine plus cisplatin for advanced non-small-cell lung cancer: the TAX 326 study group." J.Clin Oncol. 21(16):3016-3024.

Bibliography

Belani, C. P. and F. Fossella. 2005. "Elderly subgroup analysis of a randomized phase III study of docetaxel plus platinum combinations versus vinorelbine plus cisplatin for first-line treatment of advanced nonsmall cell lung carcinoma (TAX 326)." Cancer. 104(12):2766-2774.

History

Version 6

Date	Summary of changes
08/05/2020	Protocol reviewed electronically by Medical Oncology Reference Committee. Title updated to include locally advanced. Treatment schedule note updated "Consider combination immunotherapy chemotherapy regimens in patients with ECOG 0-1 and no contraindications." added. Version number changed to V.6. Review 4 years.

Version 5

Date	Summary of changes
23/07/2007	New clinical instructions added.
12/09/2009	Reviewed and transferred to eviQ.
02/07/2010	Haematological dose modifications updated (20% changed to 25% dose reduction).
12/10/2010	Dose modifications updated: "consider reducing" changed to "reduce".
19/01/2011	New format to allow for export of protocol information. Protocol version number changed to V.2. Antiemetics and premedications added to the treatment schedule.

Date	Summary of changes
	Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations. Drug specific information placed behind the drug name link.
09/09/2011	Infusion fluid for carboplatin changed from sodium chloride 0.9% to glucose 5% because of longer stability.
18/04/2012	Palonosetron added as the preferred 5HT ₃ antagonist for moderate emetogenicity.
30/11/2012	Reviewed at reference committee meeting. Needs further review. CPG link added.
26/08/2014	PHC view removed.
12/09/2014	Reviewed by Medical Oncology Reference Committee. No change. Review 2 years.
09/03/2015	Carboplatin dosing - for estimated GFR > 125 mL/min, note about measuring GFR and/or dose capping added.
07/08/2015	Efficacy table corrected to read vinorelbine cisplatin.
18/02/2016	Discussed with Medical Oncology Reference Committee chairs for review every 5 years. Next review 3 years.
31/05/2017	Transferred to new eviQ website. Version number change to v.3. Hepatitis B screening changed to NOT recommended. Antiemetic change: A NK1 receptor antagonist and a 5HT ₃ receptor antagonist in combination with dexamethasone has been added as available on the PBS for primary prophylaxis of carboplatin induced nausea and vomiting.
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.4.
17/01/2019	Carboplatin AUC ≥ 4 changed from highly to moderately emetogenic as per MASCC/ESMO and ASCO guidelines and medical oncology reference committee consensus. Dexamethasone dose reduced to daily on day 1 and 2 due to drug interaction with netupitant and day 4 dose removed. NK1 receptor antagonist unchanged. Treatment detail and clinical information updated to reflect the change. Version number changed to V.5

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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<https://www.eviq.org.au/p/226>

08 Aug 2023

Patient information - Lung cancer locally advanced or metastatic - Carboplatin and docetaxel

Patient's name:

Your treatment

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


Carboplatin and docetaxel

This treatment cycle is repeated every 21 days. Your doctor will advise you of the number of treatments you will have.

Day	Treatment	How it is given	How long it takes
1	Docetaxel (<i>dox-e-tax-elle</i>) Carboplatin (<i>carb-o-PLAT-in</i>)	By drip into a vein	2.5 hours

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.

 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
<ul style="list-style-type: none">• a temperature of 38°C or higher• chills, sweats, shivers or shakes• shortness of breath• uncontrolled vomiting or diarrhoea• pain, tingling or discomfort in your chest or arms• you become 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.
- **Docetaxel premedication:** before your treatment with docetaxel you may need to take a tablet called a premedication to help prevent you from having a reaction to docetaxel. A steroid tablet called dexamethasone may be used and should be taken with or after food as directed. The following table may be used to remind you when to take your premedication. Ask your doctor, nurse or pharmacist to fill it out for you.

Tablet	Dose	When to take

Tell your doctor or nurse if you have not taken your premedications before you have your treatment.

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.

Immediate (onset hours to days)	
Allergic reaction	<ul style="list-style-type: none"> Allergic reactions are uncommon but can be life threatening. If you feel unwell during the infusion or shortly after it, or: <ul style="list-style-type: none"> get a fever, shivers or shakes feel dizzy, faint, confused or anxious start wheezing or have difficulty breathing have a rash, itch or redness of the face <p>While you are in hospital: Tell your doctor or nurse immediately.</p> <p>After you leave: Contact your doctor or nurse immediately, or go to the nearest hospital Emergency Department.</p>
Nausea and vomiting	<ul style="list-style-type: none"> 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.
Headache	<ul style="list-style-type: none"> You can take paracetamol if you have a headache. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get a very bad headache that is not helped by pain medication.
Taste and smell changes	<ul style="list-style-type: none"> 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)	
Infection risk (neutropenia)	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> • 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.
Joint and muscle pain and stiffness	<ul style="list-style-type: none"> • You may get muscle, joint or general body pain and stiffness. • Applying a heat pack to affected areas may help. • Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain.
Diarrhoea	<ul style="list-style-type: none"> • You may get bowel motions (stools, poo) that are more frequent or more liquid. • You may also get bloating, cramping or pain. • Take your antidiarrhoeal medication as directed by your doctor. • Drink plenty of fluids (unless you are fluid restricted). • Eat and drink small amounts more often. • Avoid spicy foods, dairy products, high fibre foods, and coffee. • Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. • Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed.
Mouth pain and soreness (mucositis)	<ul style="list-style-type: none"> • You may have: <ul style="list-style-type: none"> ◦ 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: <ul style="list-style-type: none"> ◦ 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.
Tiredness and lack of energy (fatigue)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> You may notice a change in the sensations in your hands and feet, including: <ul style="list-style-type: none"> 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.
Hand-foot syndrome (palmar-plantar erythrodysesthesia)	<ul style="list-style-type: none"> The palms of your hands and soles of your feet may become: <ul style="list-style-type: none"> red and hot swollen painful and tender blistered. The skin in the area may also peel. Moisturise your hands and feet daily with sorbolene or aqueous cream. Keep your hands and feet clean and dry. Avoid hot water, instead use lukewarm water to bathe. Avoid direct sunlight. Avoid unnecessary walking, jogging or exercise. Wear cotton socks and avoid tight-fitting shoes. Tell your doctor or nurse as soon as possible if you notice any skin changes on your hands or feet.
Extra fluid in the body (fluid retention)	<ul style="list-style-type: none"> You may gain weight over a short amount of time. Your hands and feet may become swollen, appear red or feel hot and uncomfortable. These symptoms are caused by the drug docetaxel. Wear loose clothing and shoes that are not too tight. Try not to stand up or walk around too much at one time. If your ankles or legs get swollen, try raising them. Make sure that any cuts or areas of broken skin are treated as soon as possible. Tell your doctor or nurse as soon as possible if you get any of the symptoms listed above. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you become short of breath.
Eye problems	<ul style="list-style-type: none"> You may get: <ul style="list-style-type: none"> eye pain red, sore or swollen eyes blurred vision watery or gritty eyes changes in your eyesight sensitivity to sunlight. Protect your eyes from the weather (sun and wind) by wearing sunglasses, especially if you have lost your eyelashes. Tell your doctor or nurse if you get any of the symptoms listed above. Eye drops may help with your symptoms.

Late (onset weeks to months)	
Low red blood cells (anaemia)	<ul style="list-style-type: none"> You may feel dizzy, light-headed, tired and appear more pale than usual. 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)	<ul style="list-style-type: none"> 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 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
Nail changes	<ul style="list-style-type: none"> Your nails may: <ul style="list-style-type: none"> grow more slowly become darker develop ridges or white lines become brittle and flaky In some cases, you may lose your nails completely. Keep your nails clean and short. Avoid things like biting your fingernails, getting a manicure, pedicure or false nails. Wear gloves when you wash the dishes, work in the garden, or clean the house.

General advice for patients 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.

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.

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.

Where to get more information

Telephone support

- Call Cancer Council on 13 11 20 for cancer information and support
- Call the Lung Foundation Australia on 1800 654 301

Lung cancer information

- Lung Foundation Australia – lungfoundation.com.au
- Lungevity – lungevity.org

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
- Carer Help - carerhelp.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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