Non small cell lung cancer locally advanced definitive cARBOplatin and PACLitaxel chemoradiation

ID: 1436 v.7 **Endorsed** Essential Medicine List

⚠ ADDIKD Carboplatin dosing:

For dosing carboplatin, ADDIKD recommends that:

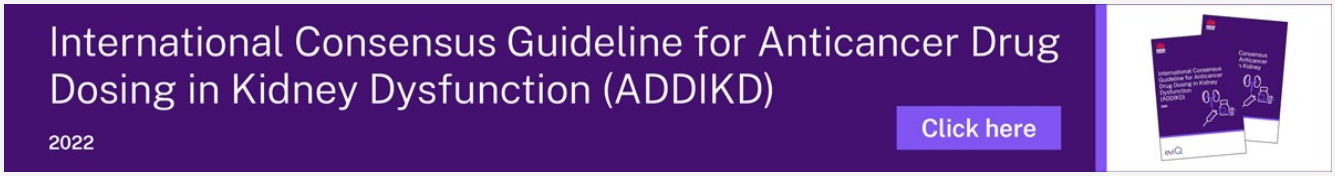
- Directly measured glomerular filtration rate (mGFR) is the preferred kidney function value in the Calvert formula, especially where estimated kidney function may be unreliable for accurate therapeutic dosing.
- Where mGFR is unavailable, eGFR adjusted to an individual's body surface area (BSA-adjusted 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 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.



Related pages:

- Respiratory non-small cell lung cancer definitive EBRT with or without chemotherapy
- Non small cell lung cancer locally advanced definitive ciSplatin and etoposide chemoradiation
- Non small cell lung cancer locally advanced durvalumab (weight based dosing) (following chemoradiation)

Treatment schedule - Overview

Cycle 1 to 6

Drug	Dose	Route	Day
PACLitaxel	45 mg/m^2	IV infusion	1
cARBOplatin	2 AUC *	IV infusion	1

*If estimated GFR is >125 mL/min (i.e. AUC 2 dose >300 mg), obtaining direct measurement rather than an estimated renal function and/or dose capping is strongly recommended

Frequency: 7 days

Cycles: 6 with concurrent radiation therapy

Drug status: All drugs in this protocol are on the PBS general schedule

Cost: ~ $30 per week

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		
Loratadine	10 mg (PO)	60 minutes before chemotherapy
Dexamethasone	8 mg (PO)	60 minutes before chemotherapy
Palonosetron	0.25 mg (IV bolus)	30 minutes before chemotherapy
PACLitaxel	45 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)
cARBOplatin	2 AUC (IV infusion)	in 500 mL glucose 5% over 30 to 60 minutes (if estimated GFR is >125 mL/min (i.e. AUC 2 dose >300 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 doses on day 2 and 3 may not be required and may be reduced or omitted at the clinicians discretion. *

Cycle 5 and 6

Day 1		
Dexamethasone	8 mg (PO)	60 minutes before chemotherapy
Palonosetron	0.25 mg (IV bolus)	30 minutes before chemotherapy
PACLitaxel	45 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)
cARBOplatin	2 AUC (IV infusion)	in 500 mL glucose 5% over 30 to 60 minutes (if estimated GFR is >125 mL/min (i.e. AUC 2 dose >300 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 doses on day 2 and 3 may not be required and may be reduced or omitted at the clinicians discretion. *

* Link to ID 7 Prevention of chemotherapy induced nausea and vomiting

Frequency: 7 days

Cycles: 6 with concurrent radiation therapy

Indications and patient population

- locally advanced non small cell lung cancer, PET scan negative for distant metastases
  - unsuitable for cisplatin and etoposide
  - ECOG performance status 0 to 1

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 paclitaxel 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. Read more about Hypersensitivity reaction
Premedication	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. Read more about premedication for prophylaxis of taxane hypersensitivity reactions
Emetogenicity MODERATE	Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy. Carboplatin AUC < 4 is classified by NCCN Guidelines v3.2018, MASCC/ESMO Antiemetic Guidelines 2016 and ASCO Antiemetic Guidelines 2017 as having moderate emetogenicity. 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. 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
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
Growth factor support	G-CSF (short or long-acting) is available on the PBS for chemotherapy induced neutropenia depending on clinical indication and/or febrile neutropenia risk. Access the PBS website
Blood tests	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.
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

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).

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 paclitaxel and carboplatin by 25% for subsequent cycles

Haematological toxicity	
Febrile neutropenia	Delay treatment until recovery and reduce paclitaxel 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 paclitaxel and carboplatin by 25% for subsequent cycles

Renal impairment	
Creatinine clearance (mL/min)	
less than 30	If using the Calvert formula, GFR should be measured rather than derived from the formula

Hepatic impairment	
Hepatic dysfunction	
Mild	Reduce paclitaxel by 25%
Moderate	Reduce paclitaxel by 50%
Severe	Omit paclitaxel

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

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

Paclitaxel		
	Interaction	**Clinical management**
CYP3A4 inhibitors (e.g. aprepitant, azole antifungals, clarithromycin, erythromycin, grapefruit juice, ritonavir etc.)	Increased toxicity of paclitaxel possible due to reduced clearance	Monitor for paclitaxel toxicity
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of paclitaxel possible due to increased clearance	Monitor for decreased clinical response to paclitaxel
CYP2C8 inhibitors (e.g. pazopanib, lapatinib, gemfibrozil, montelukast etc.)	Increased toxicity of paclitaxel possible due to reduced clearance	Monitor for paclitaxel toxicity
Metronidazole, disulfiram	Intolerance reaction to alcohol content of diluent of intravenous paclitaxel	Avoid combination
Doxorubicin	Administration schedule can influence systemic exposure to doxorubicin	Minimise by administering doxorubicin first in regimens using the combination
Cisplatin	Administration schedule may influence the development of myelosuppression	Minimise toxicity by administering paclitaxel first in regimens using the combination

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

product information monographs via the TGA website for further information.

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 required IV lines with sodium chloride 0.9%:

- low sorbing IV giving set with 0.22 micron filter must be used for paclitaxel
- attach a second IV line via a luer lock connector as close as possible to the site of injection
  - this may be required in case of a hypersensitivity reaction.

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.

Verify dexamethasone taken or administer as prescribed.

Chemotherapy - Time out

Paclitaxel

Administer paclitaxel (irritant with vesicant properties):

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

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
- hypersensitivity reactions are more common during the first 2 cycles in the first 30 minutes.

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.

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

Discharge information

Premedication

- Premedication for next cycle of chemotherapy.

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 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
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
Fatigue	Read more about fatigue
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
Oesophagitis	Inflammation of the mucosal lining of the oesophagus. It can progress to ulceration, haemorrhage, secondary infection and pain.
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
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

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 main evidence for this protocol comes from the 2010 West Japan Thoracic Oncology Group trial WJTOG 0105.[1] The aim of study was to compare newer 3rd generation regime with standard second generation regime. 456 patients were randomised to 1 of 3 arms. Arm A mitomycin/vindesine/cisplatin at full doses for 3 cycles, concurrent with 69 Gy. Arm B- carboplatin/irinotecan weekly with 60 Gy followed by 2 cycles full dose carboplatin/irinotecan. Arm C weekly paclitaxel and carboplatin with 60 Gy followed by 2 cycles full dose carboplatin/paclitaxel. With patients followed for more than 3 years, 5 year overall survival was equivalent as was median survival for the 3 arms. Toxicity slightly favoured carboplatin/paclitaxel.

A randomised phase III controlled trial reported by Carter et al 2012 compared the effects of either maintenance therapy with weekly paclitaxel or observation which involved no additional chemotherapy. This was preceded by combined modality regimen involving 2 cycles of induction therapy of paclitaxel and carboplatin and then concurrent paclitaxel, carboplatin and radiation therapy in both arms for patients with locally advanced inoperable non-small cell lung cancer (NSCLC).[2]

A randomised phase II study reported by Wang et al 2012 compared the cisplatin and etoposide (PE) concurrent with radiation therapy regimen with weekly paclitaxel and carboplatin (PC) concurrent with radiation therapy in patients with unresectable stage III NSCLC. Both arms were followed by consolidation treatment which consisted of either a platinum-based doublet chemotherapy regimen or a single agent chemotherapy regimen.[3]

All studies had at least 2 cycles of full dose neoadjuvant/consolidation carboplatin and paclitaxel when carboplatin and paclitaxel was used concurrent with radiation therapy.[1,2,3]

Further evidence in support of this protocol is provided by the RTOG 0617[4] trial which compared standard dose versus high dose conformal radiation therapy with concurrent and consolidation carboplatin and paclitaxel with or without cetuximab. Between November 2007 and November 2011, 166 patients were randomised to receive standard dose chemoradiation therapy, 121 to high-dose chemoradiation therapy, 147 to standard chemoradiation therapy with cetuximab and 110 to high dose chemoradiation therapy plus cetuximab. Median overall survival was 25.0 months (95% CI 20.2-30.5) for those receiving cetuximab and 24 months (19.8-28.6) for those who did not, at a median follow up of 21.3 months. Neither the addition of cetuximab nor increased RT dose improved outcomes compared with carboplatin and paclitaxel and standard radiation fractionation.

An analysis of 1842 Veterans Health Administration data[5] demonstrated no difference in treatment outcomes for those treated with cisplatin and etoposide (HR 0.97; 95% CI, 0.85 to 1.10) and those treated with carboplatin and paclitaxel. Patients had similar overall survival, but cisplatin and etoposide was associated with increased morbidity.

A systematic review comparing the concurrent use of either carboplatin and paclitaxel or cisplatin etoposide with thoracic radiation in patients with stage III NSCLC found the regimens to be of similar efficacy with fewer toxicities in those treated with carboplatin and paclitaxel.[6]

Efficacy

WJTOG 0105 demonstrated median survival of 20.5, 19.8 and 22.0 months with 5 year OS of 17.5%, 17.8% and 19.8%. There was no significant difference between the 3 arms.[1]

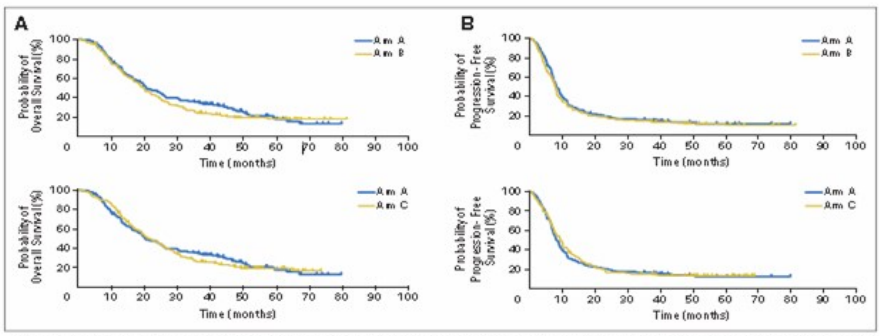
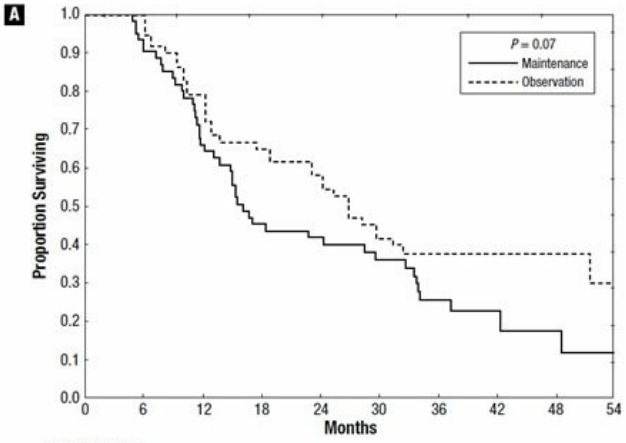


Fig 3. (A) Comparison of overall survival among the three randomly assigned arms. (B) Comparison of progression-free survival among the three randomly assigned arms.

In the Carter study the median overall survival for the maintenance arm was 16.1 months and 26.9 months for the observation arm. The median progression-free survival was 8.2 months for the maintenance arm and 10.2 months for the observation arm.[2]

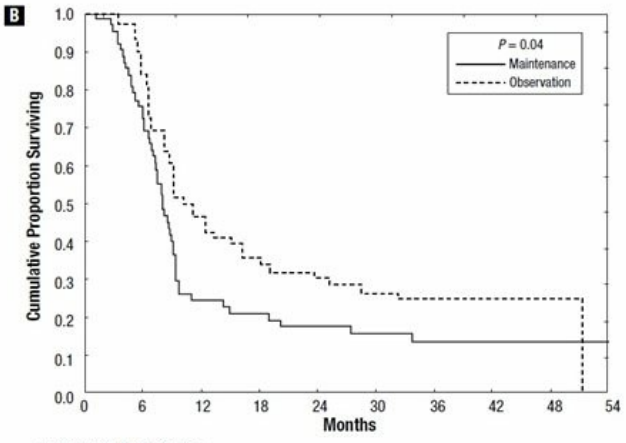
A: Overall Survival; B: Progression Free Survival
Maintenance: weekly paclitaxel 70 mg/m^2 x 3 weeks followed by 1 week of rest for 6 months.

Observation: observation for a 6-month period.



Overall Survival

Arm	N	Deaths	1 yr	2 yrs	3 yrs	4 yrs	Median	Range
Maintenance	61	45	66%	42%	25%	17%	16.1 mos.	<1–54.1 mos.
Observation	58	36	77%	58%	38%	38%	26.9 mos.	<1–58.6 mos



Progression-Free Survival

Arm	N	Prog.	1 yr	2 yrs	3 yrs	4 yrs	Median	Range
Maintenance	61	51	24%	17%	13%	13%	8.2 mos.	<1–54.1 mos.
Observation	58	44	46%	32%	25%	25%	10.2 mos.	<1–48.4 mos

The median survival time was 20.2 months in the PE arm and 13.5 months in the PC arm. The overall survival at 1,2,3 years respectively was 65.6%, 36.4%, 33.1% in the PE arm and 54.5%, 16.2%, 13% in the PC arm.

The progression-free survival at 1,2,3 years respectively was 46.9%, 21.9%, 21.9% in the PE arm and 42.4%, 13.6%, 10.2% in the PC

arm.

As the overall survival and progression-free survival were significantly higher in the PE arm than the PC arm the PC weekly regimen is not recommended over the PE regimen according to this study.[3]

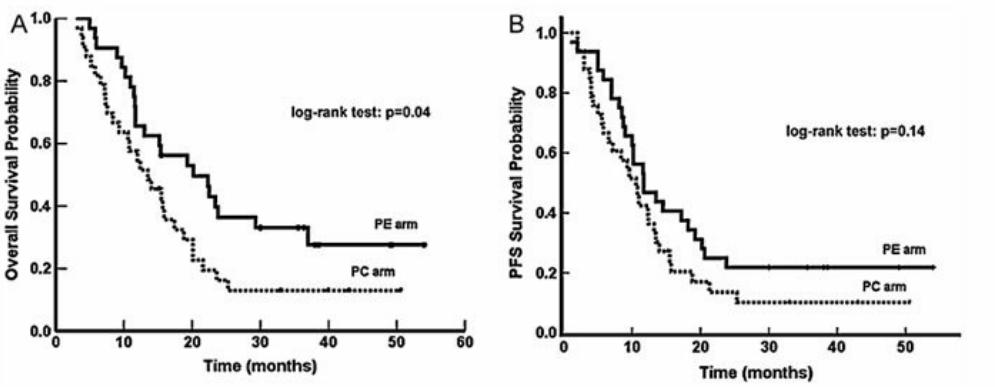


Fig. 2. (A) The overall survival (OS) and (B) the progression-free survival (PFS) curves.

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Toxicity

The following table demonstrates the toxicity of WJTO 0105[1]

Table 3. Grade 3 or Worse Toxicity

	All Treatment				Concurrent Phase			
Toxicity	Arm A	Arm B	Arm C	P	Arm A	Arm B	Arm C	P
Neutropenia	95.9	60.5	61.9	< .001	93.8	53.7	23.1	< .001
Leukopenia	96.6	75.5	66.0	< .001	95.9	72.1	45.9	< .001
Anemia	25.3	17.7	8.8	< .001	15.8	8.8	6.1	0.019
Thrombocytopenia	28.8	28.6	7.5	< .001	21.9	11.6	5.4	< .001
Febrile neutropenia	37.0	8.8	10.2	< .001	30.8	6.1	3.4	< .001
Nausea	21.9	4.8	4.8	< .001	21.9	3.4	3.4	< .001
Vomiting	6.8	2.7	0.7	.012	6.2	1.4	0.0	.001
Fatigue	13.0	6.1	4.8	.019	9.6	2.0	1.4	< .001
Constipation	11.6	6.1	2.7	.009	8.9	6.1	1.4	.015
Diarrhea	0.7	2.0	1.4	.606	0.7	0.7	0.7	.999
Neurogenic (sensory)	0.7	0.7	4.8	.017	0.0	0.0	0.0	—
Esophagitis	5.5	2.7	8.2	.121	4.1	2.0	7.5	.077
Infection	26.0	16.3	17.0	.066	22.6	12.2	10.2	.006
Dyspnea	6.2	5.4	6.1	.957	2.7	0.7	2.0	.406
Pneumonitis	1.4	4.1	4.1	.312	0.0	0.0	0.7	.368

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There were 11 treatment related deaths. Arm C (carboplatin/ paclitaxel and radiation therapy) had significantly less haematological, infection, febrile neutropenia and gastrointestinal toxicity than the standard arm A (mitomycin, vindesine and cisplatin) but more neuropathy.[2]

Carter et al[2] reported grade 3 or 4 neutropenia in 23%, fatigue in 11%, thrombocytopenia in 7% and leukopenia in 6% of patients receiving concurrent chemoradiation therapy.

Wang et al[3] reported grade 3 or 4 neutropenia as being higher in the PE arm than the PC arm, however the rate of grade 2 or greater radiation pneumonitis was higher in the PC arm than the PE arm.

The systematic review reported less haematological toxicities with carboplatin paclitaxel compared with cisplatin etoposide.[6] The incidence of greater than grade 3 toxicities associated with cisplatin etoposide v carboplatin paclitaxel for neutropenia were 54% v 23% (P<0.001), thrombocytopenia 14% v 8% (P<0.001), anaemia 14% v 9% (P=.15). Patients receiving cisplatin and etoposide experienced more nausea and vomiting than those receiving carboplatin etoposide (20% v 11% P=.03) There was no significant difference in the rates of pneumonitis (12% v 9% P=.12) or oesophagitis (23% v 21% P=.27).

References

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6 Steuer, C. E., M. Behera, V. Ernani, et al. 2017. "Comparison of Concurrent Use of Thoracic Radiation With Either Carboplatin-Paclitaxel or Cisplatin-Etoposide for Patients With Stage III Non-Small-Cell Lung Cancer: A Systematic Review." JAMA Oncol 3(8):1120-1129.

History

Version 7

Date	Summary of changes
08/02/2023	As per reference committee consensus, removed: • Ranitidine recall flag • Ranitidine from treatment schedule detail. Version number increased to V.7.

Version 6

Date	Summary of changes
08/10/2019	Clinical information updated with PBS expanded indications for GCSF.
13/12/2019	Premedication added to administration discharge information section.
17/04/2020	"Ranitidine recall" flag added.

Version 5

Date	Summary of changes
30/11/2012	New protocol taken to Medical Oncology Reference Committee meeting.
30/01/2013	Approved and published on eviQ.
25/09/2013	PHC view - Infusion time for paclitaxel corrected. Reducing premedication included as default in treatment schedule.
26/08/2014	PHC view removed.
12/09/2014	Protocol reviewed by Medical Oncology Reference Committee. No change. Next review 2 years.
08/12/2015	Interactions added in.
16/02/2016	Carboplatin dosing - for estimated GFR > 125 mL/min, note about measuring GFR and/or dose capping added.
08/04/2016	Protocol reviewed by Medical Oncology Reference Committee. Evidence updated. Review 2 years.
31/05/2017	Transferred to new eviQ website. Version number change to V.3.
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.4.

Date	Summary of changes
22/06/2018	Antiemetics updated to be in line with international guidelines. Note to dexamethasone added.
06/12/2018	Protocol reviewed by Medical Oncology Reference Committee. Title update to Non small cell lung cancer locally advanced definitive cARBOplatin and PACLitaxel chemoradiation. Evidence updated. Paclitaxel diluent changed from glucose 5% to sodium chloride 0.9%. Version updated to V.5. Review 5 years.

First approved: 30 January 2013
Last reviewed: 23 November 2018
Review due: 31 December 2023

The currency of this information is guaranteed only up until the date of printing, for any updates please check:
https://www.eviq.org.au/p/1436
07 Aug 2023

Patient information - Lung cancer advanced - Carboplatin and paclitaxel with radiation therapy

Patient's name:

Your treatment

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

Carboplatin and paclitaxel (with radiation)			
This treatment cycle is repeated every 7 days during radiation therapy (usually for 6 weeks).Your doctor will advise you of the number of treatments you will have.			
Day	**Treatment**	**How it is given**	**How long it takes**
1	**Paclitaxel** (*pak-li-TAX-el*) **Carboplatin** (*carb-o-PLAT-in*)	By drip into a vein	About 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
• 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.

- **Paclitaxel premedication:** before your treatment with paclitaxel you may need to take some tablets called a premedication to help prevent you from having a reaction to the paclitaxel. 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. Sometimes after the first 4 treatments, if you have not had a reaction to paclitaxel, you may not be required to take any premedication.

Tablet	Dose	When to take

Tell your doctor or nurse if you have not taken your premedication 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	• Allergic reactions are uncommon but can be life threatening.
	• **If you feel unwell during the infusion or shortly after it, or:**
	  ◦ **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**
	
	<u>While you are in hospital:</u> 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.

Nausea 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.**
Taste 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)	

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.**
Mouth pain and soreness (mucositis)	• You may have: ◦ 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.**
Oesophagus inflammation (oesophagitis)	• You may get heartburn or have difficult or painful swallowing. • Eat small meals that are high in protein and calories. • Avoid eating acidic, hot, salty or spicy foods, and drinking alcohol. • Sit upright when eating. • Ask to speak with a dietitian if you are having trouble eating. • **Tell your doctor or nurse as soon as possible if you have the any of the symptoms listed above and they are suddenly getting worse.**
Joint and muscle pain and stiffness	• 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	• 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.**
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.

Late (onset weeks to months)	
Low red blood cells (anaemia)	• 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)	• 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	• Your nails may: ◦ 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.

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.

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

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