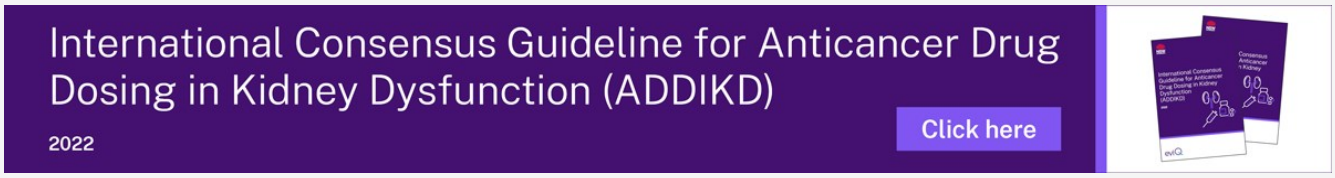
Gastric and gastroesophageal metastatic PACLitaxel and raMUCIRumab

ID: 1904 v.5 **Endorsed**

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

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:

- Gastric and gastroesophageal metastatic raMUCIRumab

Treatment schedule - Overview

Cycle 1 and further cycles

Drug	Dose	Route	Day
raMUCIRumab	8 mg/kg	IV infusion	1 and 15
PACLitaxel	80 mg/m^2	IV infusion	1, 8, 15

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

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Drug status: Paclitaxel is on the PBS general schedule

Ramucirumab is TGA approved but not PBS reimbursed for this indication

Cost: ~ $140 per cycle (paclitaxel only). Price for ramucirumab not currently available

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

Day 1		
Loratadine	10 mg (PO)	60 minutes before treatment
Dexamethasone	8 mg (PO)	60 minutes before treatment
raMUCIRumab	8 mg/kg (IV infusion)	in a final volume of 250 mL sodium chloride 0.9% over

Day 1		
		approximately 60 minutes (maximum infusion rate 25 mg/min)
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Day 8		
Loratadine	10 mg (PO)	60 minutes before treatment
Dexamethasone	4 mg (PO)	60 minutes before treatment
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Day 15		
Loratadine	10 mg (PO)	60 minutes before treatment
Metoclopramide	10 mg (PO)	one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days)
raMUCIRumab	8 mg/kg (IV infusion)	in a final volume of 250 mL sodium chloride 0.9% over approximately 60 minutes (maximum infusion rate 25 mg/min)
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Cycle 2 and further cycles

Day 1		
Loratadine	10 mg (PO)	60 minutes before treatment
Metoclopramide	10 mg (PO)	one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days)
raMUCIRumab	8 mg/kg (IV infusion)	in a final volume of 250 mL sodium chloride 0.9% over approximately 60 minutes (maximum infusion rate 25 mg/min)
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Day 8		
Metoclopramide	10 mg (PO)	one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days)
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Day 15		
Loratadine	10 mg (PO)	60 minutes before treatment
Metoclopramide	10 mg (PO)	one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days)
raMUCIRumab	8 mg/kg (IV infusion)	in a final volume of 250 mL sodium chloride 0.9% over approximately 60 minutes (maximum infusion rate 25 mg/min)
PACLitaxel	80 mg/m^2 (IV infusion)	in 250 mL sodium chloride 0.9% over 60 minutes (in non-PVC containers only)

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

Indications and patient population

Indication:

- second-line therapy for advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma in patients with disease progression after prior platinum- and fluoropyrimidine-based chemotherapy.
- ECOG performance status 0 or 1.

Cautions:

- gastrointestinal (GI) perforation, fistulae, or any significant GI or non-GI bleeding
- any arterial thromboembolic event within 6 months and/or significant venous thromboembolism within 3 months
- patients with known coronary artery disease
- uncontrolled or poorly-controlled hypertension despite standard medical management
- major surgery within 28 days of administration
- CNS metastases.

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. Hypersensitivity reactions, including acute infusion related reaction (IRR) may occur with ramucirumab. Hypersensitivity risk is greatest during the first two cycles of ramucirumab. Read more about Hypersensitivity reaction
Premedication	The product information for both paclitaxel and ramucirumab recommend that premedication is given prior to treatment to prevent hypersensitivity reactions. For ramucirumab, the product information recommends a H1 antagonist before treatment. If a patient experiences a grade 1 or 2 infusion related reaction (IRR), premedication must be given for all subsequent infusions. If a patient experiences a second grade 1 or 2 IRR despite premedication with a H1 antagonist, administer dexamethasone or equivalent; then, for subsequent infusions, premedicate with the following or equivalent medications: promethazine (intravenously), paracetamol and dexamethasone. For paclitaxel, the product information recommends a corticosteroid, antihistamine (H1 antagonist) and a H2 antagonist before treatment. Although the paclitaxel product information recommends a higher dose of dexamethasone to be used, many clinicians use a reducing premedication regimen with an anecdotally acceptable rate of hypersensitivity reactions (HSRs). 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 (infusion related reactions and anaphylaxis)

Emetogenicity LOW	Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy. Note: dexamethasone has been included both as an antiemetic and premedication for hypersensitivity in this protocol. 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
Gastrointestinal perforation	Gastrointestinal (GI) perforation has been reported in patients treated with ramucirumab. Use with caution in patients at risk of GI perforation (e.g. prior surgery or radiotherapy). Patients should be monitored for signs and symptoms of GI perforation and ramucirumab should be permanently discontinued if GI perforation occurs.
Haemorrhage	Patients treated with ramucirumab have an increased risk of haemorrhage, especially severe gastrointestinal haemorrhage. Ramucirumab should be used with caution in patients at risk of bleeding (e.g. patients with conditions predisposing to bleeding, and patients taking concurrent anticoagulant or antiplatelet medications). Ramucirumab should be permanently discontinued in patients who experience Grade 3 or 4 bleeding.
Hypertension	Ramucirumab may increase the risk of hypertension. Pre-existing hypertension should be adequately controlled prior to commencing ramucirumab. Monitor blood pressure regularly throughout treatment. Withhold ramucirumab in patients who develop hypertension until it is adequately controlled. Commence or adjust antihypertensive medication as clinically indicated. Permanently discontinue ramucirumab if medically significant hypertension cannot be controlled with antihypertensive therapy.
Proteinuria	Patients may be at increased risk of developing severe proteinuria and/or nephrotic syndrome when treated with ramucirumab. Baseline urinalysis for proteinuria is recommended prior to commencement of therapy, and throughout treatment as clinically indicated. Treatment interruption may be required if proteinuria is significant. Ramucirumab should be discontinued in the event of nephrotic syndrome. Read more about proteinuria
Thromboembolism	Serious, sometimes fatal, arterial thromboembolic events (ATEs) including myocardial infarction, cardiac arrest, cerebrovascular accident, and cerebral ischaemia have been reported in clinical trials of ramucirumab. Ramucirumab should be permanently discontinued in patients who experience a severe ATE.
Wound healing	Ramucirumab has not been studied in patients with serious or non-healing wounds. There is potential for impaired wound healing based on the mechanism of action. Ramucirumab treatment should be withheld for at least 4 weeks prior to scheduled surgery and recommenced when wounds have adequately healed. If wound healing complications occur, withhold ramucirumab until the wound is fully healed.
Reversible posterior leukoencephalopathy syndrome (RPLS)	Ramucirumab should be discontinued in patients who develop reversible posterior leukoencephalopathy syndrome (RPLS). The risk of reinitiating ramucirumab therapy in patients previously experiencing RPLS is not known. Read more about reversible posterior leukoencephalopathy syndrome (RPLS)
Blood tests	FBC, EUC and LFTs at baseline and prior to each treatment or as clinically indicated

Hepatitis B screening and prophylaxis	Routine screening for HBsAg and anti-HBc is NOT usually recommended for patients receiving this treatment. 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).

Note:

- haematological dose modifications have been adapted from the RAINBOW clinical trial[1]
- ramucirumab is not usually delayed or dose reduced.

Haematological toxicity	
Day 1	
ANC x 10^9/L (pre-treatment blood test)	
0.5 to less than 1.5	Delay paclitaxel treatment until recovery
less than 0.5	Delay paclitaxel treatment until recovery 1st occurrence: consider reducing paclitaxel dose by 10 mg/m^2 for subsequent cycles 2nd occurrence: consider reducing paclitaxel dose by a further 10 mg/m^2 for subsequent cycles
Febrile neutropenia	Delay paclitaxel treatment until recovery 1st occurrence: consider reducing paclitaxel dose by 10 mg/m2 for subsequent cycles

Haematological toxicity	
	2nd occurrence: consider reducing paclitaxel dose by a further 10 mg/m^2 for subsequent cycles
Platelets x 10^9/L (pre-treatment blood test)	
50 to less than 100	Delay paclitaxel treatment until recovery
less than 50	Delay paclitaxel treatment until recovery 1st occurrence: consider reducing paclitaxel dose by 10 mg/m^2 for subsequent cycles 2nd occurrence: consider reducing paclitaxel dose by a further 10 mg/m^2 for subsequent cycles
Day 8 and 15*	
ANC x 10^9/L (pre-treatment blood test)	
0.5 to less than 1.0	Omit paclitaxel dose
less than 0.5	Omit paclitaxel dose 1st occurrence: consider reducing paclitaxel dose by 10 mg/m^2 for subsequent cycles 2nd occurrence: consider reducing paclitaxel dose by a further 10 mg/m^2 for subsequent cycles
Platelets x 10^9/L (pre-treatment blood test)	
50 to less than 75	Omit paclitaxel dose
less than 50	Omit paclitaxel dose 1st occurrence: consider reducing paclitaxel dose by 10 mg/m^2 for subsequent cycles 2nd occurrence: consider reducing paclitaxel dose by a further 10 mg/m^2 for subsequent cycles

***Note:** On day 8 or 15, paclitaxel treatment should be omitted rather than delayed.

Renal impairment	
Mild or moderate	No dose reductions are recommended
Severe	No dose reductions are recommended for paclitaxel No safety data available for ramucirumab

Hepatic impairment	
Hepatic dysfunction	
Mild	Reduce paclitaxel by 25%.
Moderate	Reduce paclitaxel by 50%
Severe	Omit paclitaxel. Use ramuciumab with caution in patients with severe liver cirrhosis (Child-Pugh B or C), cirrhosis with hepatic encephalopathy, clinically significant ascites due to cirrhosis, or hepatorenal syndrome. Use only if potential benefits outweigh the potential risk of progressive hepatic failure

Peripheral neuropathy	
Grade 2 which is present at the start of the next cycle	Reduce paclitaxel by 25%, If persistent, 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 the dose for subsequent cycles as follows: 1st occurrence: No dose reduction 2nd occurrence: Reduce paclitaxel by 25%

Mucositis and stomatitis	
	3rd occurrence: Reduce paclitaxel by 50% 4th occurrence: Omit paclitaxel
Grade 3 or Grade 4	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: 1st occurrence: Reduce paclitaxel by 50% 2nd occurrence: Omit paclitaxel

Cease ramucirumab if any of the following occur:

- infusion-related reaction (IRR) greater than or equal to grade 3
- haemorrhagic event greater than or equal to grade 3
- arterial thromboembolic event
- gastrointestinal perforation or fistula formation
- uncontrolled severe hypertension or hypertensive crisis
- proteinuria > 3 g/24 hours or nephrotic syndrome
- episode of reversible posterior leukoencephalopathy syndrome (RPLS)

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*

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

Ramucirumab

No pharmacokinetic interactions were observed between ramucirumab and paclitaxel.

Ramucirumab
No other drug-drug interaction studies have been performed.

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: 3 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%:

- a separate line with a protein-sparing 0.22 micron filter must be used for ramucirumab
- 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 premedication taken or administer as prescribed.

Verify taxane premedication taken or administer as prescribed.

Administer antiemetics if required

Treatment - Time out

Ramucirumab

- ramucirumab is only compatible with 0.9% sodium chloride

Prior to administration check

- blood pressure
- baseline urinalysis for protein and repeat as clinically indicated (read more about proteinurea)

Administer ramucirumab:

- via IV infusion over approximately 60 minutes (maximum infusion rate 25 mg/min)
- observe for signs of infusion related reactions
- flush with ~100 mL sodium chloride 0.9%.

Stop infusion at first sign of a reaction:

- if a grade 1 or 2 (mild to moderate) infusion related reaction occurs reduce the infusion rate by 50% for the duration of the infusion and all subsequent infusions
- if a grade 3 or 4 (severe to life threatening) infusion related reaction occurs seek medical attention immediately and permanently discontinue ramucirumab.

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.

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.

Remove IV cannula and/or deaccess TIVAD or CVAD.

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

Day 8

Approximate treatment time: 90 minutes

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.

Administer antiemetics if required

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.

Remove IV cannula and/or deaccess TIVAD or CVAD.

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

Day 15

Approximate treatment time: 3 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%:

- a separate line with a protein-sparing 0.22 micron filter must be used for ramucirumab
- 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 premedication taken or administer as prescribed.

Verify taxane premedication taken or administer as prescribed.

Administer antiemetics if required

Treatment - Time out

Ramucirumab

- ramucirumab is only compatible with 0.9% sodium chloride

Prior to administration check

- blood pressure
- baseline urinalysis for protein and repeat as clinically indicated (read more about proteinurea)

Administer ramucirumab:

- via IV infusion over approximately 60 minutes (maximum infusion rate 25 mg/min)
- observe for signs of infusion related reactions
- flush with ~100 mL sodium chloride 0.9%.

Stop infusion at first sign of a reaction:

- if a grade 1 or 2 (mild to moderate) infusion related reaction occurs reduce the infusion rate by 50% for the duration of the infusion and all subsequent infusions
- if a grade 3 or 4 (severe to life threatening) infusion related reaction occurs seek medical attention immediately and permanently discontinue ramucirumab.

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.

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.

Remove IV cannula and/or deaccess TIVAD or CVAD.

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

Discharge information

Antiemetics

- Antiemetics as prescribed.

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
Taste and smell alteration	Read more about taste and smell changes
Headache	

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
Abdominal pain	Dull ache, cramping or sharp pains are common with some anti-cancer drugs. These are caused by either increased or decreased gastrointestinal motility and can be associated with diarrhoea or constipation.
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
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
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
Skin rash	Anti-cancer drugs can cause a number of changes in the skin with maculo-papular rash the most common type of drug-induced skin reaction. Read more about skin rash
Fluid retention and oedema	An excess amount of fluid around the cells, tissues or serous cavities of the body, leading to swelling.
Hypertension	High blood pressure is commonly associated with many anti-cancer drugs. Pre-existing hypertension should be controlled prior to initiation of drugs capable of causing hypertension.
Proteinuria	Read more about proteinuria
Haemorrhage	
Epistaxis	Acute bleeding from the nostril(s), nasal cavity, or nasopharynx.
Thromboembolism	Arterial and venous thromboembolic events, including pulmonary embolism, deep vein thrombosis and cerebrovascular accidents can occur. Patients should be carefully assessed for risk factors, and consideration given for antithrombotic prophylaxis in high risk patients.
Gastrointestinal perforation	A rupture of the wall of the stomach, small intestine or large bowel. Symptoms include acute abdominal pain, tenderness and signs of sepsis.
Reversible posterior leukoencephalopathy syndrome (RPLS)	A neurological disorder which may present with headache, seizures, lethargy, confusion, blindness and/or other visual and neurological disturbances. Mild to severe hypertension may also occur. Read more about reversible posterior leukoencephalopathy syndrome (RPLS)

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 protocol is provided by a phase 3 multicentre, international, randomised trial (RAINBOW) involving 658 patients comparing ramucirumab plus paclitaxel to paclitaxel plus placebo in patients with unresectable locally-advanced, or metastatic gastric or gastro-oesophageal junction adenocarcinoma.[1]

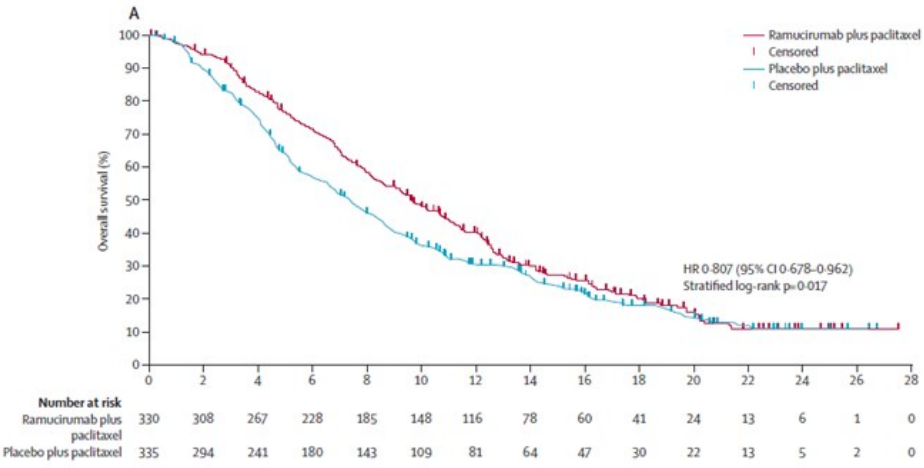
Between Dec 2010 and Sept 2012, 665 patients were randomised in a 1:1 ratio to receive ramucirumab 8 mg/kg or placebo intravenously on days 1 and 15, plus paclitaxel 80 mg/m^2 intravenously on days 1,8, and 15 of a 28-day cycle. Patients received treatment until disease progression, unacceptable toxicity or withdrawal of consent.[1]

The primary end point was overall survival (OS) and secondary end points were progression-free survival (PFS), objective tumour response, disease control, patient-reported outcomes, immunogenicity, and safety.[1]

Efficacy

The median OS was 9.6 months in the ramucirumab-paclitaxel group vs 7.4 months in the placebo-paclitaxel group (HR=0.807; 95% CI 0.678 to 0.962; p=0.017).[1]

Kaplan-meier curve of overall survival (OS)



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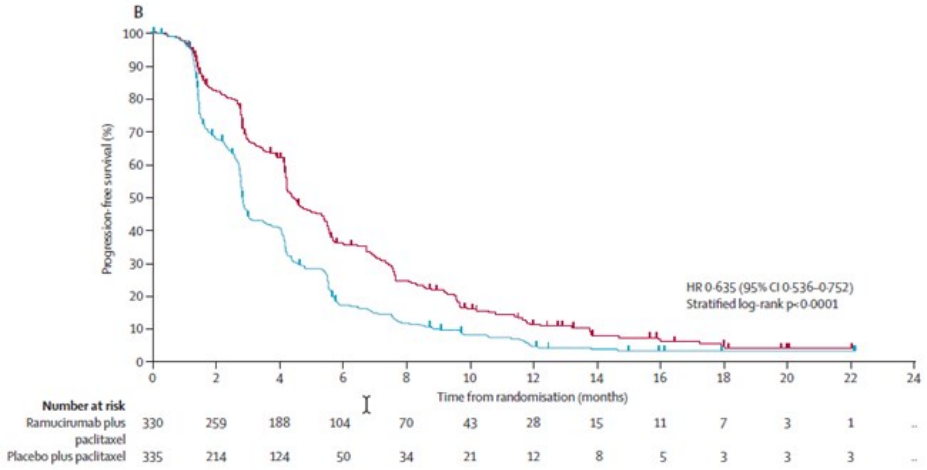
The median PFS was 4.4 months in the ramucirumab-paclitaxel group vs 2.9 months in the placebo-paclitaxel group (stratified HR 0.635; 95% CI 0.536 to 0.752; p<0.0001).[1]

Kaplain-meier analysis of progression-free survival (PFS)



Objective response rates were higher in the ramucirumab-paclitaxel arm (28%), than the placebo-paclitaxel arm (16%); p=0.0001.[1]

Best overall response

	Ramucirumab plus paclitaxel (N=330)	Placebo plus paclitaxel (N=335)
Best overall response		
Complete response	2 (<1%)	1 (<1%)
Partial response	90 (27%)	53 (16%)
Stable disease	172 (52%)	159 (47%)
Progressive disease	43 (13%)	83 (25%)
Not evaluable or not assessed	23 (7%)	39 (12%)

Data are number (%) or number (%; 95% CI), unless otherwise indicated.

Quality of life data was obtained using the QLQ-C30 and EQ-5D at baseline and at six-weekly intervals during treatment. Baseline QoL was similar between the groups. Time to deterioration (worsening of ≥10 points on each scale) was not significantly different between the groups, with a trend towards improved QoL for the ramucirumab-paclitaxel group (HR 0.798, p=0.0941). Performance score data showed a significantly longer time to deterioration in PS by both ≥1 level (HR 0.802, P=0.0444), and ≥2 levels (HR = 0.608, P=0.0063).[2]

The results of a post hoc analysis demonstrate a sustained duration of response in the ramucirumab-paclitaxel arm compared to placebo-paclitaxel arm (median 4.4 vs 2.8 months). In patients with measurable disease, improved overall response (36% vs 20%), disease control (81% vs 61%) and tumor shrinkage (78% vs 60%) rates were observed in the ramucirumab-paclitaxel arm compared to the control arm. Improved fatigue, pain, appetite loss and global QoL was seen in the ramucirumab-paclitaxel arm in patients with both stable and responding disease. Greater symptom improvement was seen in patients with tumour shrinkage.[3]

Toxicity

Grade 3 or 4 adverse events occurred more frequently in the ramucirumab plus paclitaxel group compared to the placebo plus paclitaxel group.

Although the incidence of grade 3/4 neutropenia was greater in the ramucirumab plus paclitaxel group, grade 3 or greater febrile neutropenia occurred in similar numbers in both groups (3% vs 2%).[1]

Treatment-emergent adverse events

	Ramucirumab plus paclitaxel (n=327)				Placebo plus paclitaxel (n=329)			
	Grades 1–2	Grade 3	Grade 4	Grade 5	Grades 1–2	Grade 3	Grade 4	Grade 5
Any patients with a treatment-emergent adverse event	57 (17%)	155 (47%)	73 (22%)	39 (12%)	116 (35%)	128 (39%)	27 (8%)	51 (16%)
Non-haematological adverse events								
Fatigue*	147 (45%)	39 (12%)	0	0	126 (38%)	18 (5%)	0	0
Neuropathy*	123 (38%)	27 (8%)	0	0	104 (32%)	15 (5%)	0	0
Decreased appetite	121 (37%)	10 (3%)	0	0	92 (28%)	13 (4%)	0	0
Abdominal pain*	98 (30%)	20 (6%)	0	0	87 (26%)	10 (3%)	1 (<1%)	0
Nausea	109 (33%)	5 (2%)	1 (<1%)	0	100 (30%)	8 (2%)	0	0
Alopecia	107 (33%)	0	0	0	126 (38%)	1 (<1%)	0	0
Diarrhoea	94 (29%)	12 (4%)	0	0	71 (22%)	4 (1%)	1 (<1%)	0
Epistaxis	100 (31%)	0	0	0	23 (7%)	0	0	0
Vomiting	78 (24%)	9 (3%)	1 (<1%)	0	56 (17%)	12 (4%)	0	0
Peripheral oedema	77 (24%)	5 (2%)	0	0	43 (13%)	2 (<1%)	0	0
Hypertension	32 (10%)	46 (14%)	0	0	8 (2%)	8 (2%)	0	0
Constipation	70 (21%)	0	0	0	69 (21%)	2 (<1%)	0	0
Stomatitis	62 (19%)	2 (<1%)	0	0	22 (7%)	2 (<1%)	0	0
Pyrexia	56 (17%)	3 (<1%)	0	0	36 (11%)	1 (<1%)	0	0
Proteinuria	50 (15%)	4 (1%)	0	0	20 (6%)	0	0	0
Malignant neoplasm progression	5 (2%)	16 (5%)	4 (1%)	27 (8%)	1 (<1%)	24 (7%)	1 (<1%)	34 (10%)
Weight decreased	39 (12%)	6 (2%)	0	0	45 (14%)	4 (1%)	0	0
Dyspnoea	34 (10%)	8 (2%)	0	0	29 (9%)	2 (<1%)	0	0
Rash*	42 (13%)	0	0	0	31 (9%)	0	0	0
Cough	40 (12%)	0	0	0	25 (8%)	0	0	0
Back pain	35 (11%)	4 (1%)	0	0	35 (11%)	5 (2%)	0	0
Hypoalbuminaemia*	32 (10%)	4 (1%)	0	0	13 (4%)	2 (<1%)	0	1 (<1%)
Myalgia	34 (10%)	0	0	0	32 (10%)	1 (<1%)	0	0
Ascites	21 (6%)	11 (3%)	1 (<1%)	0	14 (4%)	13 (4%)	0	0
Headache	32 (10%)	0	0	0	21 (6%)	1 (<1%)	0	0
Haematological adverse events								
Neutropenia*	45 (14%)	71 (22%)	62 (19%)	0	40 (12%)	51 (16%)	11 (3%)	0
Anaemia*	84 (26%)	30 (9%)	0	0	85 (26%)	31 (9%)	3 (<1%)	0
Leucopenia*	54 (17%)	52 (16%)	5 (2%)	0	47 (14%)	19 (6%)	3 (<1%)	0
Thrombocytopenia*	38 (12%)	5 (2%)	0	0	14 (4%)	6 (2%)	0	0

Data are number (%), unless otherwise stated. *Consolidated adverse event category comprising synonymous MEdDRA preferred terms.

References

1 Wilke, H., K. Muro, E. Van Cutsem, et al. 2014. "Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (RAINBOW): a double-blind, randomised phase 3 trial." Lancet Oncol 15(11): 1224-1235.

2 Al-Batran, S. E., E. Van Cutsem, S.C. Oh, et al. 2016. "Quality-of-life and performance status results from the phase III RAINBOW study of ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated gastric or gastroesophageal junction adenocarcinoma." Ann Oncol 27(4): 673-679.

3 Cascinu, S., G. Bodoky, K. Muro, et al. 2020. "Tumor Response and Symptom Palliation from RAINBOW, a Phase III Trial of Ramucirumab Plus Paclitaxel in Previously Treated Advanced Gastric Cancer." Oncologist.

History

Version 5

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

Date	Summary of changes
	Version number increased to V.5.

Version 4

Date	Summary of changes
01/03/2021	Premedication in clinical information section updated. Efficacy section updated to include RAINBOW trial post hoc analysis data. Version number changed to V.4.

Version 3

Date	Summary of changes
10/09/2020	Patient information title updated- 'stomach or gastroesophageal junction cancer metastatic' added. Version number changed to V.3.

Version 2

Date	Summary of changes
16/02/2018	New protocol discussed at medical oncology reference committee meeting.
21/03/2018	Protocol approved and published on eviQ. Review protocol in 1 year.
06/12/2018	Paclitaxel diluent changed from glucose 5% to sodium chloride 0.9%. Version change to V.2.
20/05/2019	Protocol reviewed electronically by the Medical Oncology Reference Committee. No changes. Review 5 years
17/04/2020	"Ranitidine recall" flag added.

First approved: 21 March 2018
Last reviewed: 20 May 2019
Review due: 30 June 2024

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/1904
13 Jul 2023

Patient information - Stomach or gastroesophageal junction cancer metastatic - Paclitaxel and ramucirumab

Patient's name:

Your treatment

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

Paclitaxel and ramucirumab			
This treatment cycle is usually repeated every 28 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	**Ramucirumab** *(RA-mue-SIR-ue-mab)* **Paclitaxel** *(pak-li-TAX-el)*	By a drip into a vein	About 3 hours
8	**Paclitaxel**	By a drip into a vein	About 1.5 hours
15	**Ramucirumab** **Paclitaxel**	By a drip into a vein	About 3 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.

Surgery and wound healing

This treatment may affect wound healing. Tell your doctor if you are planning to have surgery or have a wound that has not healed.

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.
- **Ramucirumab premedication:** before your treatment with ramucirumab you may need to take a tablet called a premedication to help prevent you from having a reaction to the ramucirumab.
- **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.

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.

Headache

- 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.**

Immediate (onset hours to days)

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.**

Stomach pain

- You may get:
  - dull aches
  - cramping or pain
  - bloating or flatulence (gas).
- **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have stomach pain that you are unable to control.**

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.**

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.**

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.

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.

Skin rash

- You may get a red, bumpy rash and dry, itchy skin.
- Moisturise your skin with a gentle non-perfumed moisturising cream like sorbolene or aqueous cream.
- Do not scratch your skin.
- Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and sunscreen of SPF 50 or higher.
- **Talk to your doctor or nurse about other ways to manage your skin rash.**

Extra fluid in the body (fluid retention)

- You may gain weight over a short amount of time.
- Your hands and feet may become swollen, appear red or feel hot and uncomfortable.
- 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 or gain 1 to 2 kg in a week.**
- **Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you become short of breath.**

High blood pressure (hypertension)

- You may not have any signs or symptoms if you have high blood pressure.
- If it is severe you may get headaches, shortness of breath or feel dizzy.
- Your blood pressure will be taken regularly during your treatment.
- **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the signs or symptoms listed above.**

Kidney changes or damage

- This treatment may cause changes to how your kidneys work. This may cause protein in your urine.
- This is not something that you will notice.
- You will have blood and urine tests to check that your kidneys are working properly.

Bleeding (haemorrhage)

- Tell your doctor or nurse if you have a wound that does not heal.
- **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:**
  - **unusual bleeding or bruising**
  - **bright red or black, tarry bowel motions (stools, poo)**
  - **stomach pain**
  - **slurred speech**
  - **shortness of breath**
  - **a fast heartbeat.**

Nose bleeds

- If your nose starts to bleed gently apply pressure on the soft part of nostrils below the bridge of the nose for at least 10 minutes.
- It may help to put a cold pack over your forehead or the bridge of the nose.
- **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if your nose will not stop bleeding.**

Blood clots (thromboembolism)

- Blood clots can occur with this 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:
- **redness, heat or pain in your leg(s)**
- **numbness or weakness in your face, arm or leg**
- **chest pain**
- **sudden shortness of breath**
- **dizziness**
- **trouble speaking**
- **blurred vision**
- **severe headache**
- **unexplained falls or loss of balance.**

Bleeding into stomach or bowel

- This side effect is rare, but can be very serious.
- **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of these signs or symptoms:**
  - **severe stomach pain**
  - **swollen and hot skin around your stomach**
  - **bleeding**
  - **nausea or vomiting**
  - **fever or chills**
  - **a fast heartbeat**
  - **you feel short of breath.**

Changes in the way your brain works [reversible posterior leukoencephalopathy syndrome (RPLS)]

- This treatment can have an effect on your brain, but this is rare.
- **Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:**
  - **headaches or vision problems**
  - **nausea and vomiting**
  - **tiredness**
  - **confusion**
  - **fits (seizures)**
  - **high blood pressure.**

Early (onset days to weeks)

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.

Late (onset weeks to months)

General advice for people having cancer treatment

Chemotherapy safety

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

Blood clot risk

- Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).
- Tell your doctor if you have a family history of blood clots.
- A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.
- If you have any of these symptoms go to your nearest hospital Emergency Department.

Medications and vaccinations

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

Other medical and dental treatment

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

Diet

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

Fertility

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

Pregnancy and breastfeeding

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

Sex life and sexuality

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

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

Stomach and oesophageal cancer information

- Pancare Foundation – pancare.org.au

General cancer information and support

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

Quit smoking information and support

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

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

Additional notes:

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

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