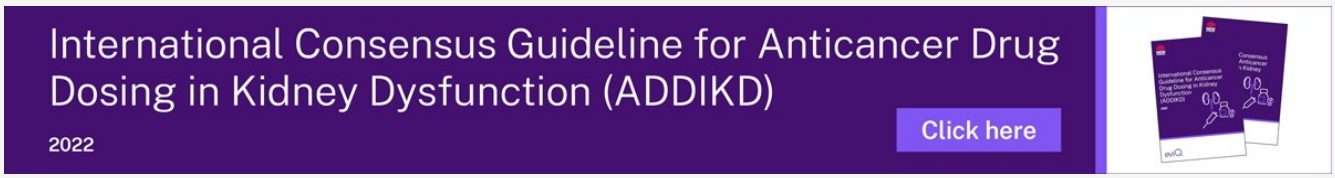
Renal cell metastatic temsirolimus

ID: 91 v.5 **Endorsed**

⚠ Ranitidine recall:
The TGA has suspended the registration of all ranitidine medicines. Further information is available from the TGA safety alert. Ranitidine is included as a default premedication in eviQ protocols and alternative approaches should be considered based on assessment of individual patients, institutional policy and availability of alternative drugs [e.g. famotidine - see ID 3264 Premedication for prophylaxis of taxane hypersensitivity reactions (infusion related reactions and anaphylaxis)]. Refer to BOPA Position Statement - H2 antagonists in paclitaxel pre-medication regimens for more information.

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.



Treatment schedule - Overview

Cycle 1 and further cycles

Drug	Dose	Route	Day
Temsirolimus	25 mg	IV infusion	1

Frequency: 7 days

Cycles: Continuous until disease progression or unacceptable toxicity

Drug status: **Temsirolimus** is TGA registered but not PBS listed

Cost: ~ $1,240 per cycle

Treatment schedule - Detail

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

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

Cycle 1 and further cycles

Day 1		
Metoclopramide	10 mg (PO)	one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days)
Promethazine	12.5 mg (IV)	30 minutes before treatment

Day 1		
Ranitidine	50 mg (IV)	in 50 mL to 100 mL sodium chloride 0.9% over 15 to 20 minutes 30 minutes before treatment
Temsirolimus	25 mg (IV infusion)	in 250 mL sodium chloride 0.9% over 30 to 60 minutes (in non-PVC containers only)

Frequency: 7 days

Cycles: Continuous until disease progression or unacceptable toxicity

Indications and patient population

- Advanced or recurrent renal cell carcinoma (RCC) in patients with no previous systemic treatment and a poor prognosis (link to Risk Stratification for Survival in Metastatic Renal Cell Carcinoma)

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 temsirolimus.
Premedication	The product information states that premedication is required for this treatment. Please refer to the treatment schedule for suggested premedication regimen. This may be substituted to reflect institutional policy.
Emetogenicity LOW	Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy. Ensure that patients also have sufficient antiemetics for breakthrough emesis: Metoclopramide 10 mg three times a day when necessary (maximum of 30 mg/24 hours, up to 5 days) OR Prochlorperazine 10 mg PO every 6 hours when necessary. Read more about preventing anti-cancer therapy induced nausea and vomiting
Infections	Patients may be immunosuppressed and should be carefully observed for the occurrence of infections, including opportunistic infections.
Pneumonitis	There have been cases of non-specific interstitial pneumonitis, including rare fatal reports, occurring in patients who have received this treatment. Read more about pulmonary toxicity associated with anti-cancer drugs.
Hyperglycaemia	Hyperglycaemia has been observed with this treatment. Close monitoring of blood sugar levels is recommended. Initiation of antidiabetic therapy may be required. In patients with pre-existing diabetes, dose adjustment of oral antidiabetic medications or insulin may be required.
Hyperlipidaemia	Hyperlipidaemia is a common adverse event. Dose adjustment or initiation of lipid-lowering agents may be required.
Wound healing	This treatment may impair wound healing and temporary interruption of treatment is recommended in patients undergoing major surgical procedures. Resume treatment based on clinical judgement of adequate wound healing.
Blood tests	FBC, EUC, LFTs, BSL and lipid studies at baseline, repeat FBC weekly, EUC and LFTs monthly. Repeat lipid studies and BSL 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: Temsirolimus is converted to sirolimus by CYP3A4. Sirolimus is the active agent, which binds to and selectively inhibits mTORC1 (mammalian target of rapamycin complex 1). It does not bind to mTORC2. Inhibition is reversible and activity is related to duration of exposure above a critical concentration. Sirolimus is extensively metabolised in the liver. It is a P-gp substrate and is also metabolised by CYP3A4. Renal elimination of both compounds is minimal.

Haematological toxicity	
ANC x 10^9/L (pre-treatment blood test)	
less than 1.0	Delay treatment until recovery and consider reducing temsirolimus by 5 mg for subsequent cycles
Febrile neutropenia	Delay treatment until recovery and consider reducing temsirolimus by 5 mg for subsequent cycles
Platelets x 10^9/L (pre-treatment blood test)	
75 to less than 100	Refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if patient is clinically well.

Haematological toxicity	
50 to less than 75	Delay treatment until recovery
less than 50	Delay treatment until recovery and consider reducing temsirolimus by 5 mg for subsequent cycles

Renal impairment
No dose modification necessary

Hepatic impairment	
Hepatic dysfunction	
Severe	Patients with severe hepatic dysfunction were excluded from the trial

Mucositis and stomatitis	
Grade 3	Delay treatment until toxicity has resolved to Grade 2 or less and reduce the dose for subsequent cycles as follows: 1st occurrence: Reduce temsirolimus by 5 mg 2nd occurrence: Reduce temsirolimus by a further 5 mg 3rd occurrence: Omit temsirolimus
Grade 4	Omit temsirolimus

Diarrhoea	
Grade 3	Delay treatment until toxicity has resolved to Grade 2 or less and reduce the dose for subsequent cycles as follows: 1st occurrence: Reduce temsirolimus by 5 mg 2nd occurrence: Reduce temsirolimus by a further 5 mg 3rd occurrence: Omit temsirolimus
Grade 4	Omit temsirolimus

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*

Temsirolimus		
	Interaction	**Clinical management**
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, cyclosporin, grapefruit juice etc.)	Increased toxicity of temsirolimus, and/or its metabolite sirolimus, possible due to reduced clearance	Avoid combination or monitor for temsirolimus toxicity If concomitant use cannot be avoided, consider reducing temsirolimus weekly dose from 25 mg to 12.5 mg
CYP3A4 and P-gp inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort, dexamethasone etc.)	Reduced efficacy of temsirolimus, and/or its metabolite sirolimus, possible due to increased clearance	Avoid combination or monitor for decreased clinical response to temsirolimus If concomitant use cannot be avoided, consider increasing temsirolimus weekly dose from 25 mg to 50 mg
Drugs undergoing P-gp-mediated elimination (e.g. digoxin, dabigatran, loperamide, phenytoin etc.)	Increased effects/toxicity of these drugs possible due to inhibition of P-gp by temsirolimus resulting in reduced clearance	Caution advised if combination used - monitor for increased effect/toxicity of interacting drugs
ACE inhibitors	Risk of angioneurotic oedema (including delayed reactions occurring two months following initiation of therapy)	Avoid combination
Potassium lowering drugs (e.g. thiazide diuretics, amphotericin)	Additive risk of hypokalaemia with temsirolimus	Avoid combination or monitor potassium level and for signs of hypokalaemia

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: 60 minutes

Safe handling and waste management

Safe administration

General patient assessment prior to each day of treatment.

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

Prime IV line(s).

Insert IV cannula or access TIVAD or CVAD.

Treatment - Time out

Temsirolimus

Prior to administration:

- administer premedication at least 30 minutes before temsirolimus.

Administer temsirolimus:

- via IV infusion over 30 to 60 minutes
- use an inline filter with non- PVC tubing
- protect from light
- flush with ~ 50 mL of sodium chloride 0.9%
- infusion should be completed within 6 hours from the commencement of the infusion
- infusion sets and bags made of soft plastic such as ethylene vinyl acetate should not be used due to the potential to lose drug over time
- if a patient develops a hypersensitivity reaction despite premedication, the infusion should be stopped and the patient should be observed for at least 30 to 60 minutes
- if rechallenge indicated, premedicate patient and recommence temsirolimus at a slower rate (up to 60 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.

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
Nausea and vomiting	Read more about prevention of treatment induced nausea and vomiting

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
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
Diarrhoea	Read more about treatment induced diarrhoea
Anorexia	Loss of appetite accompanied by decreased food intake. Read more about anorexia
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.
Hyperlipidaemia and hypercholesterolaemia	Abnormally elevated levels of lipids and cholesterol in the blood.
Hyperglycaemia	High blood sugar, an excess of glucose in the blood stream.
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.
Nephrotoxicity	Renal dysfunction resulting from damage to the glomeruli, tubules or renal vasculature.
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

Late (onset weeks to months)	
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood. Read more about anaemia
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
Pulmonary toxicity	Pulmonary toxicity may include damage to the lungs, airways, pleura and pulmonary circulation. Read more about pulmonary toxicity associated with anti-cancer drugs

Evidence

The evidence supporting this regimen comes from a three-arm multicenter, randomised phase III trial, reported by Hudes et al[1]

Between July 2003 to April 2005, 626 patients at high risk of relapse, were enrolled in the study. 209 were randomised to receive 25 mg of IV temsirolimus weekly, 207 to receive 3 million units of interferon alfa (increasing to 18 million units) subcutaneously three times a week, and 210 to receive a combination of 15 mg of temsirolimus weekly plus 6 million units of interferon alfa three times a week.

The primary end point was overall survival. Secondary end points were progression free survival, objective response rate and the clinical benefit rate.

The INTORSECT trial demonstrated no statistically significant progression free survival advantage for temsirolimus compared with sorafenib (4.3 vs 3.9 months repsecitvely P=0.19) or overall response rate following first line sunitinib. The difference in overall survival was significant in favour of sorafenib (stratified HR 1.31; 95% CI 1.05 to 1.63; two sided P=0.01). Median overall survival in the temsirolimus and sorafenib arms was 12.3 and 16.6 months respectively.[2]

Further to this the INTORACT trial demonstrated that temsirolimus/bevacizumab combination was not superior to interferon/bevacizumab for first line treatment in clear-cell metastatic renal cell carcinoma.[3]

Efficacy

Patients who received temsirolimus alone had longer overall survival (hazard ratio for death, 0.73; p=0.008) and progression free survival (p<0.001) than patients who received interferon alone.

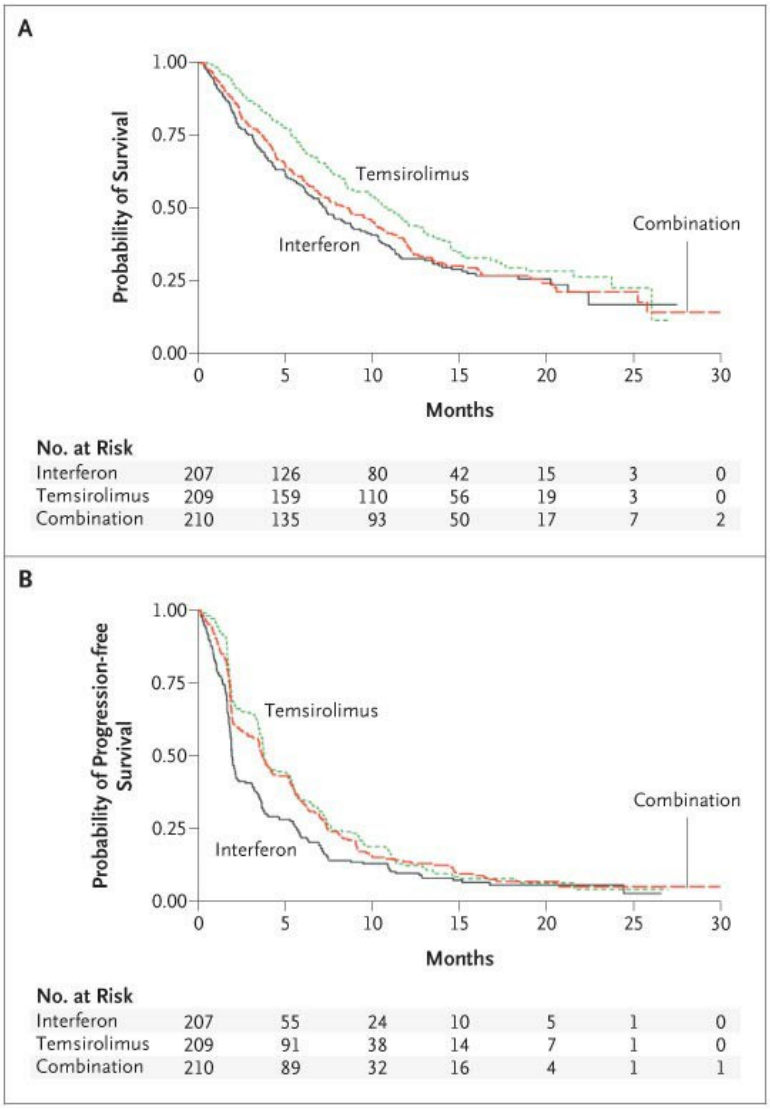
Overall, the combination group did not differ significantly from that in the interferon group (hazard ratio, 0.96; p=0.70)

Hudes[1]	Temsirolimus alone (n=209)	Interferon alfa alone (n=207)	Temsirolimus plus interferon alfa (n=210)
Overall survival	10.9 months	7.3 months	8.4 months
Progression free survival*	3.8 months	1.9 months	3.7 months
Objective response rate	8.6%	4.8%	8.1%
Clinical benefit rate**	32.1%	15.5%	28.1%

** PFS as determined by the site investigators*

***Objective response or stable disease for ≥ 24 weeks*

Kaplan-Meier Estimates of Overall Survival and Progression-free Survival[1]



Toxicity

Rash, peripheral oedema, hyperglycaemia and hyperlipidaemia were more common in the patients receiving temsirolimus, whereas asthenia was more common in the groups receiving interferon. There were fewer patients with grade 3 or 4 adverse events in the temsirolimus group (67%) than in the interferon group (78%)(p=0.02).

23% and 66% of the patients in the temsirolimus group required a dose reduction and dose delay respectively[1]

Table 3. Adverse Events Occurring in at Least 20% of Patients in Any Group.*

Adverse Event	Interferon (N=200)		Temsirolimus (N=208)		Interferon plus Temsirolimus (N=208)	
	All Grades	Grade 3 or 4	All Grades	Grade 3 or 4	All Grades	Grades 3 or 4
	percentage of patients					
Asthenia	64	26	51	11	62	28
Rash	6	0	47	4	21	1
Anemia	42	22	45	20	61	38
Nausea	41	4	37	2	40	3
Anorexia	44	4	32	3	38	8
Pain	16	2	28	5	20	6
Dyspnea	24	6	28	9	26	10
Hyperlipidemia	14	1	27	3	38	8
Infection	14	4	27	5	34	11
Diarrhea	20	2	27	1	27	5
Peripheral edema	8	0	27	2	16	0
Hyperglycemia	11	2	26	11	17	6
Cough	14	0	26	1	23	2
Hypercholesterolemia	4	0	24	1	26	2
Fever	50	4	24	1	60	3
Abdominal pain	17	2	21	4	17	3
Stomatitis	4	0	20	1	21	5
Constipation	18	1	20	0	19	0
Back pain	14	4	20	3	15	2
Vomiting	28	2	19	2	30	2
Weight loss	25	2	19	1	32	6
Headache	15	0	15	1	22	0
Increased creatinine level	10	1	14	3	20	3
Thrombocytopenia	8	0	14	1	38	9
Chills	30	2	8	1	34	1
Increased aspartate amino-transferase level	14	4	8	1	21	4
Neutropenia	12	7	7	3	27	15
Leukopenia	17	5	6	1	31	9

* The patients in this analysis did not include those who underwent randomization but received no treatment: seven in the interferon group, one in the temsirolimus group, and two in the combination-therapy group.

References

1 Hudes, G., M. Carducci, P. Tomczak, et al. 2007. "Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma." N Engl J Med 356(22):2271-2281.

2 Hutson, T., Escudier, B. & Esteban, E. 2014. "Randomized Phase III Trial of Temsirolimus Versus Sorafenib As Second-Line Therapy After Sunitinib in Patients With Metastatic Renal Cell Carcinoma." J Clin Oncol 32(8);760-7.

3 Rini, B., Bellmunt, J & Clancy, J. et al. 2014."Randomized Phase III Trial of Temsirolimus and Bevacizumab Versus Interferon Alfa and Bevacizumab in Metastatic Renal Cell Carcinoma: INTORACT Trial". J Clin Oncol. 32(8);752-9.

History

Version 5

Date	Summary of changes
23/03/2010	Approved and transferred to eviQ.
22/03/2011	New format to allow for export of protocol information. Protocol version number changed to *V.2.* Antiemetics and premedications added to the treatment schedule. Emetogenicity changed to low as per MASCC guidelines 2010. Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations. Drug specific information placed behind the drug name link.
16/01/2012	PHC view updated.
30/11/2012	Protocol reviewed at Medical Oncology Reference Committee meeting. No changes and next review in 2 years.
09/05/2014	Protocol reviewed by the Medical Oncology Reference Committee electronically. No changes. PHC view removed. Next review 2 years.
31/03/2017	Protocol discussed and decided to have a 5 year review period. Next due for review in 2019.
31/05/2017	Transferred to new eviQ website. Protocol version number changed to V.3. Hepatitis screening changed to not recommended.
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.4.
27/03/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 15/03/2019. Patient information updated- your treatment and when to get help changed to less chemotherapy focused information. Version number changed to V.5. Next review in 5 years.
17/04/2020	"Ranitidine recall" flag added.
09/11/2021	Patient information title changed to "Kidney cancer advanced or metastatic".

First approved: 23 March 2010
Last reviewed: 15 March 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/91
19 Jun 2023

Patient information - Kidney cancer advanced or metastatic - Temsirolimus

Patient's name:

Your treatment

It is important to understand that temsirolimus is not a traditional chemotherapy drug and has a different way of working. It works by targeting the cancer cells to stop them growing and spreading. The treatment schedule below explains how the drug for this treatment is given.

Temsirolimus			
This treatment cycle is repeated every 7 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	**Temsirolimus** (*TEM-sir-OH-li-mus*)	By a drip into a vein	About 1 hour

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 suddenly become unwell.

Emergency contact details

Ask your doctor or nurse from your treating team when you should get help and who to contact if you have a problem

Daytime: .....

Night/weekend: .....

Other instructions: .....

.....

.....

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. Tell your doctor if you are on an anticoagulant (medication used

to treat or prevent blood clots) e.g. warfarin. You may need to have additional blood tests.

Other medications given during this treatment

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

Side effects

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

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

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

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.**
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.**
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.**

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.**
Appetite loss (anorexia)	• You may not feel like eating. • Try to avoid drinking fluids at meal times. • Try to eat small meals or snacks regularly throughout the day. • Try to eat food that is high in protein and calories. • If you are worried about how much food you can eat, or if you are losing weight, ask to speak to a dietitian.
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.**
High blood cholesterol levels	• This treatment may increase your blood cholesterol levels. This is not a side effect you will notice. • Your cholesterol levels will be checked during your treatment.
High blood sugar level (hyperglycaemia)	• You may feel thirsty and need to urinate more often than normal. • You may get repeated infections, especially thrush. • If you are a diabetic you will need to have your blood sugar levels checked more often. You may also need to have your diabetes medication increased. • **Tell your doctor or nurse if you get any of the signs or 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.**

Kidney damage	• This treatment can cause changes to how your kidneys work. • You will have blood tests to make sure your kidneys are working properly. • You may need to drink more fluids while you are having treatment. Your doctor or nurse will tell you if you need to do this. • **Tell your doctor or nurse as soon as possible if you notice that your urine changes colour or you don't need to empty your bladder as often.**
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.

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.**
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.
Lung problems	• Lung problems are rare, but can be serious. They may occur throughout treatment or after the completion of treatment. • You may get: ◦ shortness of breath ◦ fever ◦ dry cough ◦ wheezing ◦ fast heartbeat ◦ chest pain. • Your doctor will monitor how well your lungs are working during your treatment. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have chest pain or become short of breath.**

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

Kidney cancer information

- Kidney Cancer Association – kidneycancer.org/
- Kidney Health Australia – kidney.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

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The currency of this information is guaranteed only up until the date of printing, for any updates please check:
https://www.eviq.org.au/pi/91
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