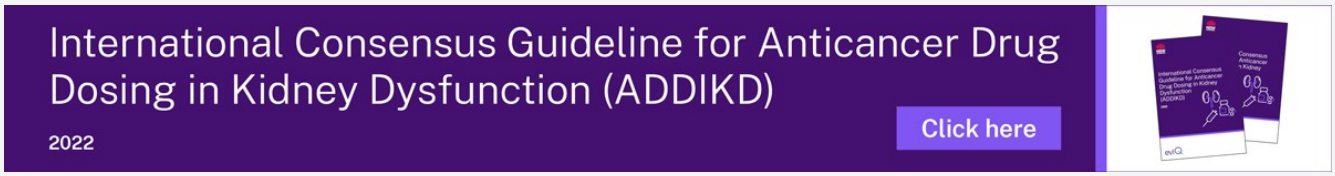
Prostate metastatic zoledronic acid

ID: 552 v.4 **Endorsed** Essential Medicine List

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:

- Prostate metastatic denosumab

Treatment schedule - Overview

Cycle 1 and further cycles

Drug	Dose	Route	Day
Zoledronic acid	4 mg	IV infusion	1

- all patients should receive oral calcium supplementation of at least 500mg and oral vitamin D supplementation of at least 400 international units daily unless hypercalcaemia is present

Frequency: 12 weeks (cycles of 28 days also acceptable)

Cycles: Continuous

Notes:
A randomised trial including 689 patients with prostate cancer found non-inferior efficacy for a 12 week dosing interval compared to a 4 week dosing interval.[1]

Drug status: **Zoledronic acid** is PBS authority

Cost: ~ $70 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		
Calcium	500 mg (PO)	ONCE a day (daily oral supplement of at least calcium 500 mg is required)
Vitamin D	400 International Units (PO)	ONCE a day (daily oral supplement of at least vitamin D 400 international units is required)
Zoledronic acid	4 mg (IV infusion)	in 100 mL sodium chloride 0.9% over at least 15 minutes

Day 2 to 84		
Calcium	500 mg (PO)	ONCE a day (daily oral supplement of at least calcium 500 mg is required)
Vitamin D	400 International Units (PO)	ONCE a day (daily oral supplement of at least vitamin D 400 international units is required)

Frequency: 12 weeks (cycles of 28 days also acceptable)

Cycles: Continuous

Indications and patient population

- Bone metastases from castration-resistant prostate cancer where there is demonstration of biochemical progression of disease despite maximal therapy with hormonal treatment

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
Dental review	Dental review prior to treatment and 6 monthly dental review during treatment is recommended to minimise risk of osteonecrosis of the jaw. Read more about medication-related osteonecrosis of the jaw (MRONJ)
Electrolyte imbalances	If hypocalcaemia, hypophosphataemia or hypomagnesaemia occurs short term supplemental therapy may be necessary. Patients who have undergone thyroid surgery may be particularly susceptible to developing hypocalcaemia due to relative hypoparathyroidism. Severe electrolyte imbalances may require hospital admission and aggressive intravenous replacement. Daily oral supplements of at least calcium 500 mg and vitamin D 400 International Units is required (unless contraindicated) for the duration of the therapy.
Renal impairment	Bisphosphonates have been associated with the development of kidney dysfunction and kidney failure. Patients should have serum creatinine assessed prior to each dose and ensure that they are adequately hydrated prior to treatment.
Length of treatment	It is unclear whether continuing the drug is of benefit once a skeletal related event has occurred.
Blood tests	EUC, calcium, magnesium and phosphate at baseline and prior to each treatment.
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.

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 .

Renal impairment	
Baseline creatinine clearance (mL/min)	**Recommended dose**
greater than 60	4 mg
50 to 60	3.5 mg
40 to 49	3.3 mg
30 to 39	3 mg
less than 30	Not recommended
Baseline serum creatinine (micromol/L)	
265 or greater	Not recommended

*Treatment should be withheld for deterioration in renal function (increase of serum creatinine greater than 45 micromol/L in patients with normal baseline * or increase of serum creatinine greater than 90 micromol/L in patients with abnormal baseline). Resumption of therapy may be considered when serum creatinine returns to within 10% of baseline.*

** serum creatinine less than 125 micromol/L*

Hepatic impairment
Limited clinical data in severe hepatic insufficiency therefore no specific recommendations

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*

Zoledronic acid		
	Interaction	**Clinical management**
Thalidomide	Increased risk of kidney dysfunction	Monitor kidney function
Anti-angiogenic drugs (e.g. sunitinib, bevacizumab)	Increased risk of osteonecrosis of the jaw	Monitor for development of osteonecrosis of the jaw if used in combination
Nephrotoxic drugs (e.g. aminoglycosides, amphotericin, contrast dye, frusemide, NSAIDs)	Additive nephrotoxicity	Monitor kidney function
Drugs that may cause hypocalcaemia (e.g. aminoglycosides, loop diuretics, other bisphosphonates, cinacalcet, phenytoin etc.)	Additive effect with zoledronic acid	Avoid combination or monitor calcium levels closely; ensure calcium and vitamin D supplementation is occurring (unless hypercalcaemic)

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: 30 minutes

Safe handling and waste management (reproductive risk only)

Safe administration

Prime IV line(s).

Insert IV cannula or access TIVAD or CVAD.

Treatment - Time out

Zoledronic acid

Prior to administration:

- ensure creatinine has been checked
- ensure patient is adequately hydrated
- do not administer if the patient is dehydrated.

Administer zoledronic acid (irritant):

- via IV infusion over 15 minutes (infusion times of less than 15 minutes should be avoided)
- flush with ~ 50 mL of sodium chloride 0.9%.

Note: There may be a synergistic effect between chemotherapy and zoledronic acid. If chemotherapy is being administered, it should be administered before the zoledronic acid.

Remove IV cannula and/or deaccess TIVAD or CVAD.

Continue safe handling precautions (reproductive risk only) for 7 days after completion of drug(s).

Discharge information

Supplements

- Daily oral supplements of calcium 500 mg and vitamin D 400 International Units are recommended.

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)	
Flu-like symptoms	
Headache	

Early (onset days to weeks)	
Fatigue	Read more about fatigue
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

Delayed (onset months to years)	
Osteonecrosis of the jaw (ONJ)	Exposed, necrotic bone in the maxillofacial region is associated with IV bisphosphonates and denosumab. It can persist for more than 8 weeks. Read more about medication-related osteonecrosis of the jaw

Evidence

There is conflicting evidence regarding efficacy of bisphosphonates on reducing skeletal related events (SRE: pathological fracture, cord compression or requirement for surgery or radiation of bony metastases, or hypercalcemia) or bone pain in prostate cancer.

A randomised study of 8 mg and 4 mg of zoledronic acid compared to placebo demonstrated a reduction in number of SRE's and prolongation of time to first SRE.[2] There was little impact on quality of life or analgesic score. Because of a higher incidence of elevated creatinine, the protocol was amended to reduce the 8 mg dose to 4mg. This trial used routine imaging rather than symptomatic investigation to document SRE, and radiation to bone was counted as an SRE.

These results contrast that of a study of pamidronate disodium (APD), where no effect was seen on bone pain or reduction in SRE using clinical endpoints.[3] In this study, radiation to symptomatic bone metastases was seen as 'routine care' and not counted as an SRE.

Evidence for the dosing interval is from CALGB (Alliance) 70604,[1] a phase III randomised, open-label, non-inferiority trial. 1822 bisphosphonate-naïve cancer patients with at least one site of bone involvement (breast n = 855, prostate n = 689, multiple myeloma n = 278) were enrolled. In the prostate cancer subgroup, 345 patients were randomised to the 4 weekly treatment group and 344 patients to the 12 weekly treatment group. The primary end point was the proportion of patients with at least one SRE at 2 years. Secondary end points included the proportion of patients with at least one SRE by disease type.

The CALGB 70604 study showed non-inferiority for the 12 weekly interval arm compared with the 4 weekly arm for SRE within 2 years. The prostate cancer between-group proportion difference was 0.02 (99.9% CI, −0.10 to 0.14); $P = .59$)). There was no difference in serum bone turnover marker profiles.[1]

Summary of efficacy[1]

Table 2. Skeletal-Related Events (SRE) by Disease Site[a]

Disease Site by Zoledronic Acid Dose Group	No. of Patients	Follow-up, No. (%)				Intent-to-Treat Analysis[c]			Sensitivity Analysis[d]		
		Completed 2 y		Dropped Out Before 2 y[b]							
		SRE	No SRE	SRE	No SRE	No. (%) With Aggregated SRE	Proportion Difference (4-wk Dose Group Minus 12-wk Dose Group) in SRE	P Value[e]	No. (%) With Aggregated SRE	Proportion Difference (4-wk Dose Group Minus 12-wk Dose Group) in SRE	P Value[e]
Total											
Every 4 wk	911	113 (6)	295 (16)	147 (8)	356 (20)	616 (68)	0 (1-sided 95% CI, −0.04 to ∞)	<.001[f]	260 (29)	0.01 (1-sided 95% CI, −0.03 to ∞)	<.001[f]
Every 12 wk	911	95 (5)	292 (16)	158 (9)	366 (20)	619 (68)			253 (28)		
Breast Cancer											
Every 4 wk	427	57 (7)	155 (18)	57 (7)	158 (18)	272 (64)	−0.05 (99.9% CI, −0.16 to 0.05)	.50	114 (27)	−0.02 (99.9% CI, −0.13 to 0.09)	.58
Every 12 wk	428	46 (5)	132 (16)	76 (9)	174 (20)	296 (69)			122 (29)		
Prostate Cancer											
Every 4 wk	345	36 (5)	85 (12)	74 (11)	150 (22)	260 (75)	0.03 (99.9% CI, −0.08 to 0.15)	.59	110 (32)	0.02 (99.9% CI, −0.10 to 0.14)	.58
Every 12 wk	344	35 (5)	98 (14)	67 (10)	144 (21)	246 (72)			102 (30)		
Multiple Myeloma											
Every 4 wk	139	20 (7)	55 (20)	16 (6)	48 (17)	84 (60)	0.05 (99.9% CI, −0.15 to 0.25)	.14	36 (26)	0.06 (99.9% CI, −0.12 to 0.24)	.35
Every 12 wk	139	14 (5)	62 (22)	15 (6)	48 (17)	77 (55)			29 (21)		

[a] Skeletal-related events were defined as clinical fracture, spinal cord compression, radiation to bone, and surgery involving bone.

[b] Includes participants without SRE forms as indicated in Figure 1.

[c] Analysis assumes dropouts without at least 1 SRE had SRE.

[d] Analysis assumes dropouts without at least 1 SRE did not have SRE.

[e] Cochran-Mantel-Haenszel test for any between-group difference adjusted for cancer type, baseline serum creatinine level, prior SRE, and prior use of oral bisphosphonates.

[f] Indicates noninferiority.

The rate of adverse events in the CALGB 70604 study were comparable between the two dosing interval arms and between the breast, prostate and multiple myeloma groups. Osteonecrosis of the jaw occurred in 2% of patients in the 4 weekly arm and 1% of patients in the 12 weekly arm. Renal adverse events (grade 3 or 4 increase in creatinine level) occurred in 1.2% of patients in the 4 weekly arm and 0.5% of patients in the 12 weekly arm.[1]

References

1 Himelstein, A. Foster, J. J. Khatcheressian et al. 2017. "Effect of longer-interval vs standard dosing of zoledronic acid on skeletal events in patients with bone metastases". JAMA. 2017;317(1):48-58

2 Saad, F., D. M. Gleason, R. Murray, et al. 2004. "Long-term efficacy of zoledronic acid for the prevention of skeletal complications in patients with metastatic hormone-refractory prostate cancer." J.Natl.Cancer Inst. 96(11):879-882.

3 Small, E. J., M. R. Smith, J. J. Seaman, et al. 2003. "Combined analysis of two multicenter, randomized, placebo-controlled studies of pamidronate disodium for the palliation of bone pain in men with metastatic prostate cancer." J.Clin Oncol 21(23):4277-4284.

History

Version 4

Date	Summary of changes
05/01/2010	Review and transferred to eviQ.
02/07/2010	Calculator removed.
22/02/2011	New format to allow for export of protocol information. Protocol version number changed to *V.2.* Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations.
07/04/11	PHC view added.
9/1/2012	PHC view updated.
3/4/2012	Patient information updated to include ONJ.

Date	Summary of changes
23/05/2012	Calcium and vitamin D added to the treatment schedule.
08/04/2013	Link to denosumab protocol added.
09/05/2014	Protocol reviewed electronically by Medical Oncology Reference Committee; no change. PHC view removed. Next review in 2 years.
31/05/2017	Transferred to new eviQ website. Protocol version number changed to V.3. Protocol reviewed by Reference Committee: • note added regarding reducing the frequency to every 12 weeks after the first year of treatment based on reference committee consensus • note added beneath treatment table that patients should be receiving oral calcium and vitamin D supplementation • review in 2 years
21/08/2018	Frequency changed to every 12 weeks as per Reference Committee consensus. Evidence updated. Protocol version number changed to V.4.
25/03/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 15/03/2019. No changes. Next review in 5 years.

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https://www.eviq.org.au/p/552
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Patient information - Prostate cancer metastatic - Zoledronic acid

Patient's name:

Your treatment

Zoledronic acid is **not** chemotherapy. It is used to to reduce the damage caused to the bones by the cancer. It works by helping the bones to heal where damaged and increasing the strength of the bones. By doing this, it reduces pain, fractures and the need for radiation therapy to treat bone secondaries.

The treatment schedule below explains how the drug for this treatment is given.

Zoledronic acid			
This treatment cycle is repeated every 21 to 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	**Zoledronic acid** (*ZOE-le-DRON-ik AS-id*)	By a drip into a vein	About 30 minutes

When to get help

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: .....

.....

.....

.....

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

- pain, stinging, swelling or redness around the injection site
- 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

You may need to have blood tests while you are receiving this treatment. Your doctor or nurse will tell you when to have these blood tests.

Other medications given during this treatment

- **Calcium and vitamin D supplements:** you may be given some calcium and vitamin D tablets. Your doctor or nurse will tell you how and when to take these.

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)	
Flu-like symptoms	• You may get: ◦ a fever ◦ chills or sweats ◦ muscle and joint pain ◦ a cough ◦ headaches. • Tell your doctor or nurse if you get any of the symptoms listed above. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have a temperature of 38°C or higher.**
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.**

Early (onset days to weeks)	
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.**
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.

Delayed (onset months to years)	
Jaw problems (osteonecrosis of the jaw)	• You may get the following signs or symptoms during treatment, or after you have stopped treatment: ◦ pain, swelling or infection in the gums ◦ loosening of teeth ◦ numbness or heaviness in the jaw ◦ poor healing of gums and sockets, especially after dental treatment • Do your mouth care regularly. • See a dentist before you begin treatment and then for 6 monthly check ups. • Make sure you tell your dentist that you are starting treatment with a bisphosphonate or denosumab. • If you need a tooth removed, talk to your doctor first, as you will need to stop treatment 6 to 8 weeks before the dental work. Only start treatment again when the tooth socket has healed. • **Tell your doctor or dentist immediately if you get any of the symptoms listed above.**

General advice for people having cancer treatment

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.
- Vaccinations such as flu and tetanus vaccines are safe to receive while you are having treatment. If you are unsure, check with your doctor before you have any vaccinations.

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.
- 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 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.

Fathering a child

- Some cancer treatments can be dangerous to unborn babies. Talk to your doctor or nurse if you think there is any chance that your partner could be pregnant.
- Do not try to 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 fatherhood after completing this treatment, talk to your doctor. Some doctors advise waiting between 6 months and 2 years after treatment.

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

Prostate cancer information

- Continence Foundation of Australia – continence.org.au
- Healthy Male Andrology Australia – healthymale.org.au
- National Continence Management Strategy – bladderbowel.gov.au/ncp/ncms
- National Public Toilet Map – toiletmap.gov.au
- Prostate Cancer Foundation of Australia – prostate.org.au
- South Australian Prostate Cancer Clinical Outcome Collaborative – prostatehealth.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:

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