

Acute myeloid leukaemia induction 7-3-7 modified (cytarabine iDarubicin and etoposide) SUPERSEDED

ID: 351 v.3 **Superseded**

This protocol has been superseded as it is not considered best practice for this patient population. [AML Induction big ICE 7](#) days is the preferred regimen.

Patients with leukaemia should be considered for inclusion into clinical trials. Link to [ALLG website](#) and [ANZCTR 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](#).

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

2022

[Click here](#)



Related pages:

- [Acute myeloid leukaemia induction 7-3 Ida \(cytarabine and iDarubicin\)](#)
- [Acute myeloid leukaemia induction 7-3 \(cytarabine and DAUNOrubicin\)](#)

Treatment schedule - Overview

Drug	Dose	Route	Day
iDarubicin	12 mg/m ²	IV	1 to 3
Etoposide *	75 mg/m ²	IV infusion	1 to 7
Cytarabine (Ara-C)	100 mg/m ²	CIV	1 to 7

* Etopophos (etoposide phosphate) 113.6 mg is equivalent to etoposide 100 mg. Doses in this protocol are expressed as etoposide.

Cycles: 1 or 2. Usually given once but maybe repeated if remission is not achieved

Notes:

The addition of etoposide has been shown to be beneficial in patients under the age of 55 in terms of response rate, however it also increases the risk of mucositis.¹

Drug status: **Cytarabine** and **Etoposide:** [PBS General Schedule](#)
Idarubicin: [Restricted Benefit](#)

Cost: ~ \$1,340 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.

Day 1 to 3		
iDArubicin	12 mg/m ² (IV)	over 10 to 15 minutes
Etoposide	75 mg/m ² (IV infusion)	in 500 mL sodium chloride 0.9% over 30 to 60 minutes
Cytarabine (Ara-C)	100 mg/m ² (CIV)	in sodium chloride 0.9% over 24 hours as a continuous infusion

Day 4 to 7		
Etoposide	75 mg/m ² (IV infusion)	in 500 mL sodium chloride 0.9% over 30 to 60 minutes
Cytarabine (Ara-C)	100 mg/m ² (CIV)	in sodium chloride 0.9% over 24 hours as a continuous infusion

- etopophos (etoposide phosphate) 113.6 mg is equivalent to etoposide 100 mg. Doses in this protocol are expressed as etoposide.

Cycles: 1 or 2. Usually given once but maybe repeated if remission is not achieved

Indications and patient population

- Acute myeloid leukaemia, induction, for patients younger than 55 years of age.

Clinical information

Venous access	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 etoposide. Read more about Hypersensitivity reaction
Antiemetics for multi-day protocols	Antiemetic therapy should be administered throughout the duration of the chemotherapy protocol and to cover delayed nausea. The acute and delayed emetic risk of multi-day chemotherapy protocols will overlap depending on the individual drugs and their sequence of administration. More or less antiemetic cover may be required. 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

Cumulative lifetime dose of anthracyclines	<p>Cumulative doses should take into account all previous anthracyclines received during a patient's lifetime (i.e. daunorubicin, doxorubicin, epirubicin, idarubicin and mitoxantrone).</p> <p>Criteria for reducing the total anthracycline cumulative lifetime dose include:</p> <ul style="list-style-type: none"> • patient is elderly • prior mediastinal radiation • hypertensive cardiomegaly • concurrent therapy with high dose cyclophosphamide and some other cytotoxic drugs (e.g. bleomycin, dacarbazine, dactinomycin, etoposide, melphalan, mitomycin and vincristine). <p>Baseline clinical assessments include echocardiogram (ECHO) or gated heart pool scan (GHPS) and electrocardiogram (ECG) evaluation.</p> <p>Patients with normal baseline cardiac function (left ventricular ejection fraction (LVEF) > 50%) and low risk patients require LVEF monitoring when greater than 70% of the anthracycline threshold is reached or if the patient displays symptoms of cardiac impairment. Post-treatment cardiac monitoring is recommended for patients who have received high levels of total cumulative doses of anthracyclines at the clinician's discretion.</p> <p>Read more about cardiac toxicity associated with anthracyclines</p>
Cytarabine syndrome	<p>Treatment with cytarabine may cause a "cytarabine syndrome" characterised by flu-like symptoms, skin rash and occasionally chest pain.</p>
Etoposide conversion factor	<p>Note: Etopophos (etoposide phosphate) 113.6 mg is equivalent to etoposide 100 mg. Doses in this protocol are expressed as etoposide.</p>
Tumour lysis risk	<p>Assess patient for risk of developing tumour lysis syndrome.</p> <p>Read more about prevention and management of tumour lysis syndrome.</p>
Pneumocystis jirovecii pneumonia (PJP) prophylaxis	<p>Read more about prophylaxis of pneumocystis jirovecii (carinii) in cancer patients</p>
Antiviral prophylaxis	<p>Read more about antiviral prophylaxis drugs and doses</p>
Antifungal prophylaxis	<p>Read more about antifungal prophylaxis drugs and doses.</p>
Growth factor support	<p>G-CSF (short or long-acting) is available on the PBS for chemotherapy induced neutropenia depending on clinical indication and/or febrile neutropenia risk.</p> <p>Access the PBS website</p>
Blood tests	<p>FBC, EUC, eGFR and LFTs at baseline and prior to each treatment.</p>
Hepatitis B screening and prophylaxis	<p>Routine screening for HBsAg and anti-HBc is recommended prior to initiation of treatment. Prophylaxis should be determined according to individual institutional policy.</p> <p>Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy</p>
Vaccinations	<p>Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.</p> <p>Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook.</p> <p>Read more about COVID-19 vaccines and cancer.</p>
Fertility, pregnancy and lactation	<p>Cancer treatment can have harmful effects on fertility and this should be discussed with all patients of reproductive potential prior to commencing treatment. There is a risk of foetal harm in pregnant women. A pregnancy test should be considered prior to initiating treatment in females of reproductive potential if sexually active. It is important that all patients of reproductive potential use effective contraception whilst on therapy and after treatment finishes. Effective contraception methods and adequate contraception timeframe should be discussed with all patients of reproductive potential. Possibility of infant risk should be discussed with breastfeeding patients.</p> <p>Read more about the effect of cancer treatment on fertility</p>

Dose modifications

Evidence for dose modifications is limited, and the recommendations made on eviQ are intended as a guide only. They are generally conservative with an emphasis on safety. Any dose modification should be based on clinical judgement, and the individual patient's situation including but not limited to treatment intent (curative vs palliative), the anti-cancer regimen (single versus combination therapy versus chemotherapy versus immunotherapy), biology of the cancer (site, size, mutations, metastases), other treatment related side effects, additional co-morbidities, performance status and patient preferences. Suggested dose modifications are based on clinical trial findings, product information, published guidelines and reference committee consensus. The dose reduction applies to each individual dose and not to the total number of days or duration of treatment cycle unless stated otherwise. Non-haematological gradings are based on [Common Terminology Criteria for Adverse Events \(CTCAE\)](#) unless otherwise specified. Renal and hepatic dose modifications have been standardised where possible. For more information see dosing considerations & disclaimer.

The dose recommendations in kidney dysfunction (i.e. renal impairment) displayed may not reflect those in the ADDIKD guideline and have been included for historical reference only. Recommendations will be updated once the individual protocol has been evaluated by the reference committee, with this version of the protocol then being archived. Clinicians are expected to refer to the ADDIKD guideline prior to prescribing in kidney dysfunction.

[International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction \(ADDIKD\)](#).

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

Haematological toxicity

Dose reductions for haematological toxicity not usually recommended. Discuss with Haematologist. Consider adding [G-CSF](#) from Day 8.

Renal impairment

Creatinine clearance (mL/min)

10 to 50	Reduce etoposide by 25%
less than 10	Reduce etoposide by 50%

No specific dose modifications recommended for cytarabine in renal impairment, but please note an increased risk of neurotoxicity has been associated with high dose cytarabine with creatinine clearance less than 60 mL/min.

Hepatic impairment

Hepatic dysfunction

Mild	Reduce idarubicin by 25%
Moderate	Reduce idarubicin by 50%
Severe	Omit idarubicin. Consider alternative regimen

Elevations in liver function tests occur with both standard and high dose cytarabine. Significant liver function abnormalities may require discontinuation or a dose reduction

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](#)

Cytarabine		
	Interaction	Clinical management
Cytidine deaminase (CDA) inhibitors (e.g. cedazuridine)	Potential increased effect/toxicity of cytarabine due to reduced clearance	Avoid combination or monitor for increased cytarabine effect/toxicity

Etoposide and Etoposide Phosphate		
	Interaction	Clinical management
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin etc.)	Increased toxicity of etoposide possible due to reduced clearance	Avoid combination or monitor for etoposide toxicity
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of etoposide possible due to increased clearance	Avoid combination or monitor for decreased clinical response to etoposide
Glucosamine	Reduced efficacy of etoposide (due to induction of glucose-regulated stress proteins resulting in decreased expression of topoisomerase II)	Avoid combination or monitor for decreased clinical response to etoposide
Grapefruit juice	Reduced efficacy of oral etoposide possible due to possible alteration of P-gp mediated intestinal transport of etoposide	Avoid combination or monitor for decreased clinical response to etoposide

Idarubicin		
	Interaction	Clinical management
Cardiotoxic drugs (eg. calcium channel blockers, propranolol)	Increased risk of idarubicin-induced cardiotoxicity	Avoid combination or monitor closely for cardiotoxicity

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

Days 1 to 3

Safe handling and waste management

Safe administration

General patient assessment prior to each treatment.

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

Prime IV line(s).

Access CVAD.

- baseline weight
- strict fluid balance
- dipstick urinalysis prior to treatment

Hydration if prescribed

Pre treatment medication

Verify antiemetics taken or administer as prescribed.

⊕ Chemotherapy - Time out

Idarubicin

Administer idarubicin (vesicant):

- over 10 to 15 minutes
 - via a minibag **OR**
 - by IV bolus via a side port of a freely flowing IV infusion
- ensure vein is patent and monitor for signs of extravasation throughout administration
- flush with ~150 mL of sodium chloride 0.9%
- potential for flare reaction during administration of idarubicin (facial flushing and red streaking along the vein) stop infusion exclude extravasation before continuing at a slower rate of infusion.

Although rare, cardiac arrhythmias may occur during or immediately after idarubicin administration. If sudden onset of dyspnoea, palpitations or irregular pulse occurs, stop administration immediately and obtain urgent medical officer review.

Etoposide

Administer etoposide (irritant):

- via IV infusion over 30 to 60 minutes
- rapid infusion may cause hypotension
- observe for hypersensitivity
- flush with ~ 100 mL sodium chloride 0.9%
- if using etoposide phosphate administer in ~ 50 mL sodium chloride 0.9% or glucose 5% over ~15 minutes.

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.

Cytarabine

- administer via continuous IV infusion over 7 days
- hang a new bag every 24 hours
- do not interrupt the infusion of cytarabine.

Observe for symptoms of cytarabine syndrome:

- fever, myalgia, bone pain, and/or occasionally rash, chest pain, or conjunctivitis which can occur 6 to 12 hours following drug administration. Symptoms usually resolve within 24 hours after cytarabine is discontinued.
- corticosteroids may be used for treatment and prophylaxis.

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

Days 4 to 7

Safe handling and waste management

Safe administration

General patient assessment prior to each treatment.

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

- daily weight
- daily dipstick urinalysis
- strict fluid balance

Hydration if prescribed

Pre treatment medication

Verify antiemetics taken or administer as prescribed.

🕒 Chemotherapy - Time out

Etoposide

Administer etoposide (irritant):

- via IV infusion over 30 to 60 minutes
- rapid infusion may cause hypotension
- observe for hypersensitivity
- flush with ~ 100 mL sodium chloride 0.9%
- if using etoposide phosphate administer in ~ 50 mL sodium chloride 0.9% or glucose 5% over ~15 minutes.

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.

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Observe for symptoms of cytarabine syndrome:

- fever, myalgia, bone pain, and/or occasionally rash, chest pain, or conjunctivitis which can occur 6 to 12 hours following drug administration. Symptoms usually resolve within 24 hours after cytarabine is discontinued.
- corticosteroids may be used for treatment and prophylaxis.

Deaccess **CVAD**.

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

Discharge information

Antiemetics

- Antiemetics as prescribed.

Growth factor support

- Arrangements for administration if prescribed.

Prophylaxis medications

- Prophylaxis medications (if prescribed) i.e. tumour lysis prophylaxis, PJP prophylaxis, antifungals, antivirals.

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
Flare reaction	Anthracycline flare reaction is caused by a localised allergic reaction. It is characterised by erythematous vein streaking, urticaria and pruritus which may occur during drug administration and is often associated with too rapid an infusion. Extravasation must be ruled out if flare occurs.
Nausea and vomiting	Read more about prevention of treatment induced nausea and vomiting
Red-orange discolouration of urine	Pink/red/orange discolouration of the urine. This can last for up to 48 hours after some anthracycline drugs.
Taste and smell alteration	Read more about taste and smell changes
Extravasation, tissue or vein injury	The unintentional instillation or leakage of a drug or substance out of a blood vessel into surrounding tissue. This has the potential to cause damage to affected tissue. Read more about extravasation management

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
Diarrhoea	Read more about treatment induced diarrhoea
Oral mucositis	Erythematous and ulcerative lesions of the gastrointestinal tract (GIT). It commonly develops following chemotherapy, radiation therapy to the head, neck or oesophagus, and high dose chemotherapy followed by a blood and marrow transplant (BMT). Read more about oral mucositis
Fatigue	Read more about fatigue
Anorexia	Loss of appetite accompanied by decreased food intake. Read more about anorexia
Photosensitivity	Increased sensitivity to ultraviolet (UV) light resulting in an exaggerated sunburn-like reaction accompanied by stinging sensations and urticaria.
Radiation recall	Erythematous or inflammatory skin reaction resembling severe sunburn at sites previously treated with radiation therapy can occur with certain anti-cancer drugs. Symptoms include vesiculation, desquamation and ulceration of the skin. Read more about radiation recall

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
Cognitive changes (chemo fog)	Changes in cognition characterised by memory loss, forgetfulness and feeling vague. This is also referred to as 'chemo brain' or 'chemo fog'. Read more about cognitive changes (chemo fog)
Delayed (onset months to years)	
Cardiotoxicity	Anthracyclines are the most frequently implicated anti-cancer drugs associated with cardiotoxicity, which typically manifests as a reduction in left ventricular ejection fraction (LVEF), cardiomyopathy, or symptomatic CHF. Anthracycline induced cardiotoxicity has been categorised into acute, early-onset chronic progressive and late-onset chronic progressive and is usually not reversible. The risk of clinical cardiotoxicity increases with a number of risk factors including higher total cumulative doses. Read more about cardiac toxicity associated with anthracyclines

Evidence

This protocol has been superseded as it is not considered best practice for this patient population. [AML Induction big ICE 7 days](#) is the preferred regimen.

Over the last decade a number of studies have examined whether dose intensification of induction chemotherapy would improve long-term results of treatment of AML. In the ALSG M2 study,¹ 264 patients with AML were randomised to receive induction chemotherapy with either "7-3" (cytarabine and daunorubicin) (n = 132) or "7-3-7" (cytarabine, daunorubicin plus etoposide) for 7 days (n = 132), followed by 2 courses of consolidation therapy ("5-2" or "5-2-5") and 24 months of maintenance therapy. The remission rates for the 2 arms were not significantly different (56% vs 59%). However, there was a significant improvement in response duration (p = 0.007) and disease-free survival (p = 0.037) in patients receiving "7-3-7". In particular, for patients aged less than 55 years of age the estimated 5 year survival rate after achieving CR was increased from 17% for "7-3" to 30% for "7-3-7". The superiority of idarubicin over daunorubicin has been well established subsequent to the ALSG M2 study.^{2,3,4}

Efficacy

Survival curve for all eligible patients:¹

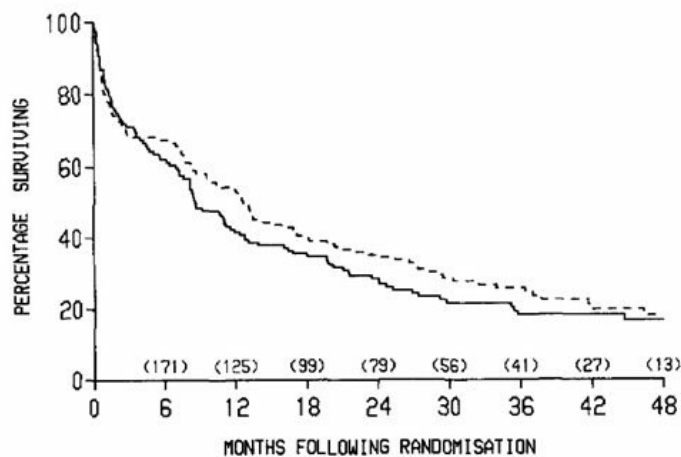


Fig 4. Survival by randomization arm for all eligible patients ($P_L = .4$, $P_a = .4$), based on ALSG 7-3 versus 7-3-7 database March 1989. Numbers in brackets refer to patients at risk at the beginning of the period. (---), ARM 737, 132 cases; (—), ARM 73, 132 cases.

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Survival of patients aged less than 55 years:¹

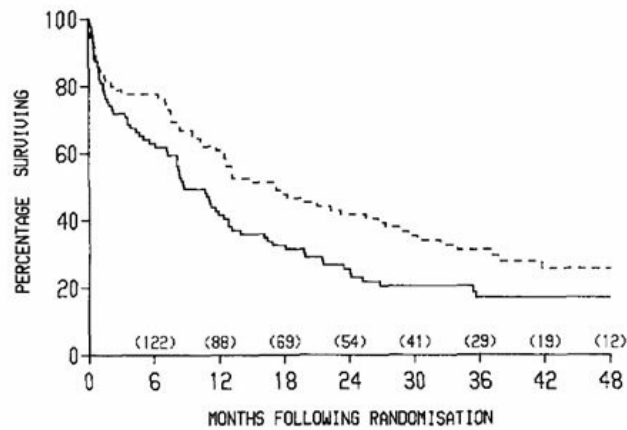


Fig 5. Survival of patients aged less than 55 years ($P_t = .03$, $P_s = .03$), based on ALSG 7-3 versus 7-3-7 database March 1989. Numbers in brackets refer to patients at risk at the beginning of the period. (---), ARM 737, 85 cases; (—), ARM 73, 89 cases.

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Toxicity

Overall, the haematological toxicities of the 7-3-7 and 7-3 induction arms were equivalent (median 16 days of granulocytopenia $<0.5 \times 10^9/L$ per course of 7-3 and median 15 days granulocytopenia $<0.5 \times 10^9/L$ per course of 7-3-7). The median number of days with thrombocytopenia $<50 \times 10^9/L$ was 15 days for both arms.¹

Non-haematological toxicities of the 7-3-7 and 7-3 induction arms were equivalent, except for significantly more diarrhoea in the 7-3-7 arm. Significantly more stomatitis was experienced by patients aged ≥ 55 years in the 7-3-7 arm (26% grade 3 to 4 stomatitis in the 7-3-7 arm vs. 7% in the 7-3 arm $P=0.2$). This was not observed in patients <55 years (13% grade 3 to 4 stomatitis in the 7-3-7 arm vs. 11% in the 7-3 arm).¹

Non-haematological adverse side effects:¹

Table 2. Nonhematologic Toxicity for 264 Patients Receiving Induction Therapy

Toxicity	Regimen	WHO Toxicity Grade ¹¹ (%)					P Value
		0	1	2	3	4	
Stomatitis	7-3	29	24	37	8	2	.34
	7-3-7	30	20	33	12	5	
Nausea and vomiting	7-3	10	30	36	22	2	.33
	7-3-7	16	32	26	26	1	
Alopecia	7-3	11	14	42	33	—	.08
	7-3-7	12	5	35	48	—	
Clinical bleeding	7-3	22	30	27	16	5	.23
	7-3-7	17	25	38	14	7	
Neuropathy	7-3	98	1	0	1	0	.56
	7-3-7	98	2	0	0	0	
Diarrhea	7-3	40	26	20	13	1	.05
	7-3-7	34	18	27	19	2	

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References

- 1 Bishop, J. F., R. M. Lowenthal, D. Joshua, et al. 1990. "Etoposide in acute nonlymphocytic leukemia. Australian Leukemia Study Group." *Blood* 75(1):27-32.
- 2 Wiernik, P. H., P. L. Banks, D. C. Case, Jr., et al. 1992. "Cytarabine plus idarubicin or daunorubicin as induction and consolidation therapy for previously untreated adult patients with acute myeloid leukemia." *Blood* 79(2):313-319.

- 3 Vogler, W. R., E. Velez-Garcia, R. S. Weiner, et al. 1992. "A phase III trial comparing idarubicin and daunorubicin in combination with cytarabine in acute myelogenous leukemia: a Southeastern Cancer Study Group Study." *J.Clin Oncol.* 10(7):1103-1111.
- 4 Berman, E., G. Heller, J. Santorsa, et al. 1991. "Results of a randomized trial comparing idarubicin and cytosine arabinoside with daunorubicin and cytosine arabinoside in adult patients with newly diagnosed acute myelogenous leukemia." *Blood* 77(8):1666-1674.

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1998 AML Collaborative Group 1998 "A systematic collaborative overview of randomized trials comparing idarubicin with daunorubicin (or other anthracyclines) as induction therapy for acute myeloid leukaemia." *Br.J Haematol.* 103(1):100-109.

History

Version 3

Date	Summary of changes
29/07/2008	Addition of information to improve the comprehensiveness including additional drug interactions, clinical considerations (management of tumour lysis syndrome)
10/03/2010	Review and transferred to eviQ
17/09/2010	Full protocol review at Haematology Reference Committee meeting: - removal of 'de novo' and changed age range to 'less than 55 years' as per Bishop et al - notes section deleted (except for etoposide point) - no longer relevant - dose modification recommendations for etoposide and cytarabine included
11/04/2012	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 Drug specific information placed behind the drug name link
27/06/2014	Superseded by the haematology reference committee. Added link to ALLG and ANZCTR with statement 'Patients with AML should be considered for inclusion into clinical trials'.
31/05/2017	Transferred to new eviQ website. Version number change to V.3.
10/10/2019	Clinical information updated with PBS expanded indications for G-CSF.

The information contained in this protocol is based on the highest level of available evidence and consensus of the eviQ reference committee regarding their views of currently accepted approaches to treatment. Any clinician (medical oncologist, haematologist, radiation oncologist, medical physicist, radiation therapist, pharmacist or nurse) seeking to apply or consult this protocol is expected to use independent clinical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use is subject to eviQ's disclaimer available at www.eviq.org.au

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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/351>

18 Oct 2023

Patient information - Acute myeloid leukaemia (AML) - Induction 7-3-7 modified (cytarabine, idarubicin, etoposide)

Patient's name:

Your treatment

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


Induction 7-3-7 modified (cytarabine, idarubicin, etoposide)

This treatment may be given for up to two cycles. Your doctor will advise you of the number of treatments you will have.

Day	Treatment	How it is given	How long it takes
1 to 3	Idarubicin (<i>EYE-da-ROO-bi-sin</i>)	By a drip into a vein	About 15 minutes
1 to 7	Etoposide (<i>e-TOE-poe-side</i>)	By a drip into a vein	About 1 hour
	Cytarabine (<i>sye-TARE-a-been</i>)	By a drip into a vein	For 7 days continuously

When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you become unwell.

 IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you have any of the following at any time:	Emergency contact details Ask your doctor or nurse from your treating team who to contact if you have a problem
<ul style="list-style-type: none">• a temperature of 38°C or higher• chills, sweats, shivers or shakes• shortness of breath• uncontrolled vomiting or diarrhoea• pain, tingling or discomfort in your chest or arms• you become unwell.	Daytime:..... Night/weekend:..... Other instructions:.....

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

- leaking from the area where the drugs are being given
- pain, stinging, swelling or redness in the area where the drugs are being given or at any injection sites
- a skin rash, itching, feeling short of breath, wheezing, fever, shivers, or feeling dizzy or unwell in any way (allergic reaction).

Other information about your treatment

Changes to your dose or treatment delays

Sometimes a treatment may be started at a lower dose or the dose needs to be changed during treatment. There may also be times when your treatment is delayed. This can happen if your doctor thinks you are likely to have severe side effects, if you get severe side effects, if your blood counts are affected and causing delays in treatment, or if you are finding it hard to cope with the treatment. This is called a dose reduction, dose change or treatment delay. Your doctor will explain if you need any changes or delays to your treatment and the reason why.

Blood tests and monitoring

You will need to have a blood test before you start treatment and regularly throughout your treatment. Your doctor or nurse will tell you when to have these blood tests.

Central venous access devices (CVADs)

This treatment involves having chemotherapy through a central venous access device (CVAD). Your doctor or nurse will explain this to you. For more information see the [eviQ patient information sheets](#) on CVADs.

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.
- **Prophylaxis medication:** you may need to take some medications to prevent infection and to help prevent or reduce some of the side effects of the chemotherapy. Your doctor or nurse will tell you how and when to take these medications.
- **G-CSF:** you may be given injection(s) of a drug called G-CSF (also called filgrastim, lipegfilgrastim or pegfilgrastim) under your skin. This helps to boost your white blood cell count. Your white blood cells help to fight infection. Lipegfilgrastim and pegfilgrastim are given once. Filgrastim is given for several days until your white blood cells recover. Your doctor will decide if you need this medication. Follow this link to read more information on [how to give this injection](#).

Superseded treatments

This treatment is superseded meaning that better treatments have taken its place. Uncommonly superseded treatments are still used. Your doctor will explain why this treatment has been selected for you.

Side effects

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

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

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

Immediate (onset hours to days)	
Allergic reaction	<ul style="list-style-type: none"> Allergic reactions are uncommon but can be life threatening. If you feel unwell during the infusion or shortly after it, or: <ul style="list-style-type: none"> get a fever, shivers or shakes feel dizzy, faint, confused or anxious start wheezing or have difficulty breathing have a rash, itch or redness of the face <p>While you are in hospital: Tell your doctor or nurse immediately.</p> <p>After you leave: Contact your doctor or nurse immediately, or go to the nearest hospital Emergency Department.</p>
Redness and itching along vein	<ul style="list-style-type: none"> You may get redness and itching along the vein where your chemotherapy is being infused. This will usually go away within 30 minutes of stopping the injection. Tell your doctor or nurse as soon as possible if you get any of the symptoms listed above. Your nurse will check to make sure the drug has not leaked out of the vein.
Nausea and vomiting	<ul style="list-style-type: none"> You may feel sick (nausea) or be sick (vomit). Take your anti-sickness medication as directed even if you don't feel sick. Drink plenty of fluids (unless you are fluid restricted). Eat small meals more frequently. Try food that does not require much preparation. Try bland foods like dry biscuits or toast. Gentle exercise may help with nausea. Ask your doctor or nurse for eviQ patient information - Nausea and vomiting during cancer treatment. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have uncontrolled vomiting or feel dizzy or light-headed.
Urine turning orange or red	<ul style="list-style-type: none"> Your urine will turn an orange or red colour. This is not harmful and should only last for up to 48 hours after treatment.
Taste and smell changes	<ul style="list-style-type: none"> You may find that food loses its taste or tastes different. These changes are likely to go away with time. Do your mouth care regularly. Chew on sugar-free gum or eat sugar-free mints. Add flavour to your food with sauces and herbs. Ask your doctor or nurse for eviQ patient information - Taste and smell changes during cancer treatment.
Pain or swelling at injection site (extravasation)	<ul style="list-style-type: none"> This treatment can cause serious injury if it leaks from the area where it is going into the vein. This can cause pain, stinging, swelling or redness at or near the site where the drug enters the vein. If not treated correctly, you may get blistering and ulceration. Tell your doctor or nurse immediately if you get any of the symptoms listed above during or after treatment.

Early (onset days to weeks)

Infection risk (neutropenia)	<ul style="list-style-type: none"> • This treatment lowers the amount of white blood cells in your body. The type of white blood cells that help to fight infection are called neutrophils. Having low level of neutrophils is called neutropenia. If you have neutropenia, you are at greater risk of getting an infection. It also means that your body can't fight infections as well as usual. This is a serious side effect, and can be life threatening. • Wash your hands often. • Keep a thermometer at home and take your temperature regularly, and if you feel unwell. • Do your mouth care regularly. • Inspect your central line site (if you have one) daily for any redness, pus or swelling. • Limit contact with people who are sick. • Learn how to recognise the signs of infection. • Ask your doctor or nurse for eviQ patient information - Infection during cancer treatment. • Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms: <ul style="list-style-type: none"> ◦ a temperature of 38°C or higher ◦ chills, shivers, sweats or shakes ◦ a sore throat or cough ◦ uncontrolled diarrhoea ◦ shortness of breath ◦ a fast heartbeat ◦ become unwell even without a temperature.
Low platelets (thrombocytopenia)	<ul style="list-style-type: none"> • This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising. • Try not to bruise or cut yourself. • Avoid contact sport or vigorous exercise. • Clear your nose by blowing gently. • Avoid constipation. • Brush your teeth with a soft toothbrush. • Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to. • Tell your doctor or nurse if you have any bruising or bleeding. • Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.
Diarrhoea	<ul style="list-style-type: none"> • You may get bowel motions (stools, poo) that are more frequent or more liquid. • You may also get bloating, cramping or pain. • Take your antidiarrhoeal medication as directed by your doctor. • Drink plenty of fluids (unless you are fluid restricted). • Eat and drink small amounts more often. • Avoid spicy foods, dairy products, high fibre foods, and coffee. • Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. • Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed.

Mouth pain and soreness (mucositis)	<ul style="list-style-type: none"> • You may have: <ul style="list-style-type: none"> ◦ bleeding gums ◦ mouth ulcers ◦ a white coating on your tongue ◦ pain in the mouth or throat ◦ difficulty eating or swallowing. • Avoid spicy, acidic or crunchy foods and very hot or cold food and drinks. • Try bland and soft foods. • Brush your teeth gently with a soft toothbrush after each meal and at bedtime. If you normally floss continue to do so. • Rinse your mouth after you eat and brush your teeth, using either: <ul style="list-style-type: none"> ◦ 1/4 teaspoon of salt in 1 cup of warm water, or ◦ 1/4 teaspoon of bicarbonate of soda in 1 cup of warm water • Ask your doctor or nurse for eviQ patient information - Mouth problems during cancer treatment. • Tell your doctor or nurse if you get any of the symptoms listed above.
Tiredness and lack of energy (fatigue)	<ul style="list-style-type: none"> • You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or things you enjoy. • Do not drive or operate machinery if you are feeling tired. • Nap for short periods (only 1 hour at a time) • Prioritise your tasks to ensure the best use of your energy. • Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted). • Try some gentle exercise daily. • Allow your friends and family to help. • Tell your doctor or nurse if you get any of the symptoms listed above.
Appetite loss (anorexia)	<ul style="list-style-type: none"> • 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.
Skin that is more sensitive to the sun (photosensitivity)	<ul style="list-style-type: none"> • After being out in the sun you may develop a rash like a bad sunburn. • Your skin may become red, swollen and blistered. • Avoid direct sunlight. • Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and a sunscreen of SPF 50 or higher. • Tell your doctor or nurse if you get any of the symptoms listed above.
Skin reaction in an area previously treated with radiation therapy (radiation recall)	<ul style="list-style-type: none"> • In the area that was treated with radiation therapy, your skin may become: <ul style="list-style-type: none"> ◦ dry, red and itchy ◦ tender and swollen • It may also: <ul style="list-style-type: none"> ◦ peel or blister ◦ form ulcers • This usually happens weeks or months after chemotherapy treatment. • Avoid wearing tight clothing. • Avoid direct sunlight and very hot or cold temperatures. • Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and a sunscreen of SPF 50 or higher. • Tell your doctor or nurse if you get any of the symptoms listed above.

Late (onset weeks to months)	
Low red blood cells (anaemia)	<ul style="list-style-type: none"> You may feel dizzy, light-headed, tired and appear more pale than usual. Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.
Hair loss (alopecia)	<ul style="list-style-type: none"> Your hair may start to fall out from your head and body. Hair loss usually starts 2 to 3 weeks after your first treatment. You may become completely bald and your scalp might feel tender. Use a gentle shampoo and a soft brush. Take care with hair products like hairspray, hair dye, bleaches and perms. Protect your scalp from the cold with a hat, scarf or wig. Protect your scalp from the sun with a hat or sunscreen of SPF 50 or higher. Moisturise your scalp to prevent itching. Ask your doctor or nurse about the Look Good Feel Better program
Chemo brain (chemotherapy-related cognitive impairment)	<ul style="list-style-type: none"> You may notice that you are unable to concentrate, feel unusually disorganised or tired (lethargic) and have trouble with your memory. These symptoms usually improve once treatment is completed. Ask your doctor or nurse for eviQ patient information – Memory changes and chemotherapy (chemo brain). Tell your doctor or nurse if you get any of the symptoms listed above.

Delayed (onset months to years)	
Heart problems	<ul style="list-style-type: none"> You may get: <ul style="list-style-type: none"> chest pain or tightness shortness of breath swelling of your ankles an abnormal heartbeat. Heart problems can occur months to years after treatment. Tell your doctor if you have a history of heart problems or high blood pressure. Before or during treatment, you may be asked to have a test to see how well your heart is working. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the symptoms listed above.

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 and food safety

- 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.
- There are some foods that may cause infection in high risk individuals and should be avoided. For further information on foods to avoid and food hygiene please ask for a copy of the [Listeria and food brochure](#).

Fertility

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

Pregnancy and breastfeeding

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

Sex life and sexuality

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

Quitting smoking

- It is never too late to quit smoking. Quitting smoking is one of the best things you can do to help your treatment work better.
- There are many effective tools to improve your chances of quitting.
- Talk to your treating team for more information and referral to a smoking cessation support service.

Staying active

- Research shows that exercise, no matter how small, has many benefits for people during and after cancer treatment.
- Talk to your doctor before starting an exercise program. Your doctor can advise whether you need a modified exercise program.

For more information about cancer treatment, side effects and side effect management see our [Patient and carers section](#).

Where to get more information

Telephone support

- Call Cancer Council on 13 11 20 for cancer information and support
- Call the Leukaemia Foundation on 1800 620 420 (Mon to Fri 9am – 5pm)
- Call the Lymphoma Nurse Support Line on 1800 953 081 (Mon to Fri 9am - 5pm)
- Call the Myeloma Australia Support Line on 1800 693 566 (Mon to Fri 9am - 5pm)

Haematology, transplant and cellular therapy information

- Arrow bone marrow transplant foundation – arrow.org.au
- Australasian Menopause Society – menopause.org.au
- Chris O'Brien Lifehouse - Total Body Irradiation - mylifehouse.org.au/departments/radiation-oncology/total-body-irradiation/
- Healthy Male Andrology Australia – healthymale.org.au/
- International Myeloma Foundation – myeloma.org
- Leukaemia Foundation – leukaemia.org.au
- Lymphoma Australia – lymphoma.org.au
- Myeloma Australia – myeloma.org.au
- NSW Agency for Clinical Innovation, Blood & Marrow Transplant Network – <https://aci.health.nsw.gov.au/networks/bmtct>
- NSW Agency for Clinical Innovation - aci.health.nsw.gov.au/projects/immune-effector-cell-service
- NCCN Guidelines for Patients Immunotherapy Side Effects: CAR T-Cell Therapy - nccn.org/patientresources/patient-resources/guidelines-for-patients
- Talk Blood Cancer – cmlsupport.org.uk/organisation-type/social-media-groups

General cancer information and support

- Australian Rare Cancer (ARC) Portal – arcportal.org.au/
- Beyondblue – beyondblue.org.au
- Cancer Australia – canceraustralia.gov.au
- Cancer Council Australia – cancer.org.au
- Cancer Voices Australia – cancervoicesaustralia.org
- CanTeen – canteen.org.au
- Carers Australia – carersaustralia.com.au
- Carer Help - carerhelp.com.au
- eviQ Cancer Treatments Online – eviQ.org.au
- Food Standards Australia New Zealand: Listeria & Food Safety – foodstandards.gov.au/publications/pages/listeriabrochuretext.aspx
- 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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