

# Acute lymphoblastic leukaemia Ph+ maintenance therapy (daSATinib prednisolone vinCRISTine)

ID: 3532 v.1 Under review Essential Medicine List

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

This protocol is based on limited evidence; refer to the evidence section of this protocol for more information.

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 lymphoblastic leukaemia Ph+ hyper CVAD and daSATinib Part A and B/maintenance overview](#)
- [Acute lymphoblastic leukaemia Ph+ hyper CVAD part A and daSATinib](#)
- [Acute lymphoblastic leukaemia Ph+ hyper CVAD Part B and daSATinib](#)

## Treatment schedule - Overview

### Cycle 1 and further cycles

Drug	Dose	Route	Day
daSATinib	100 mg ONCE a day	PO	1 to 28
Prednisolone	200 mg ONCE a day	PO	1 to 5
vinCRISTine	2 mg	IV infusion	1

**Frequency:** 28 days

**Cycles:** Continuous for a total of 2 years (24 months); dasatinib is then continued indefinitely as a sole agent.

### Notes:

In the original trial by Ravandi et al.<sup>1</sup>, maintenance treatment was interrupted with two intensifications of hyper CVAD and dasatinib during months 6 and 13; it is the consensus of the Haematology Reference Committee to omit these intensifications from the eviQ protocol.

**Drug status:** Dasatinib is [PBS authority](#)

All other drugs are on the [PBS general schedule](#)

Dasatinib is available as **20 mg, 50 mg, 70 mg** and **100 mg** tablets

Prednisolone is available as **25 mg, 5 mg** and **1 mg** tablets

**Cost:** ~ \$2,870 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		
daSATinib	100 mg (PO)	ONCE a day with or without food.
Prednisolone	200 mg (PO)	ONCE a day on days 1 to 5. Take in the morning with food.
vinCRISTine	2 mg (IV infusion)	in 50 mL sodium chloride 0.9% over 5 to 10 minutes via minibag
Day 2 to 5		
daSATinib	100 mg (PO)	ONCE a day with or without food.
Prednisolone	200 mg (PO)	ONCE a day on days 1 to 5. Take in the morning with food.
Day 6 to 28		
daSATinib	100 mg (PO)	ONCE a day with or without food.

**Frequency:** 28 days

**Cycles:** Continuous for a total of 2 years (24 months); dasatinib is then continued indefinitely as a sole agent.

## Indications and patient population

### Indications:

- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) maintenance therapy after completion of hyper CVAD Parts A and B with dasatinib

### Caution:

- Not generally for treatment of Philadelphia chromosome negative acute lymphoblastic leukaemia, refer to:
  - [Hyper CVAD Part A and B/POMP](#)

## Clinical information

<b>Safety alert vincristine administration</b>	For safe administration of vincristine refer to the safety alert issued by the <a href="#">Australian Commission on Safety and Quality in Health Care</a>
<b>Venous access required</b>	IV cannula (IVC) or central venous access device (CVAD) is required to administer this treatment. Read more about <a href="#">central venous access device line selection</a>
<b>Caution with oral anti-cancer drugs</b>	Select links for information on the safe prescribing, dispensing and administration of orally administered anti-cancer drugs. Read more about the <a href="#">COSA guidelines</a> and <a href="#">oral anti-cancer therapy</a>
<b>Emetogenicity minimal or low</b>	No routine prophylaxis required. If patients experience nausea and/or vomiting, consider using the low emetogenic risk regimen. Read more about <a href="#">preventing anti-cancer therapy induced nausea and vomiting</a>

<b>Administration details</b>	Long-term suppression of gastric secretions may decrease the absorption of some tyrosine kinase inhibitors (TKIs). Patients should avoid taking H2-receptor antagonists or proton-pump inhibitors while undergoing therapy with this TKI. Antacids may be used instead, but should be avoided within 2 hours of the TKI dose.
<b>Prolongation of QT interval</b>	<p>This treatment may prolong the QT interval and increase the risk of cardiac arrhythmia. Use with caution in patients with a congenital long QT syndrome, patients treated with a high cumulative dose of anthracycline therapy, patients taking medications that may prolong the QT interval and those with electrolyte disturbances. Risk factors (e.g. electrolyte abnormalities) should be corrected, where possible, prior to commencement of treatment and the concurrent use of drugs that may prolong the QT interval should be avoided. Baseline and periodic monitoring of electrocardiogram (ECG) and electrolytes (potassium, magnesium, calcium) should be considered in patients at high risk of QT prolongation.</p> <p>Read more about drugs that may prolong QTc interval at <a href="https://crediblemeds.org">crediblemeds.org</a> (registration required).</p>
<b>Cardiac toxicity</b>	<p>Tyrosine kinase inhibitors have been associated with cardiac complications of varying degrees and severity.</p> <p>Patients, especially those with pre-existing cardiovascular disease, should have a baseline cardiac assessment including an electrocardiogram (ECG) and biochemistry and be closely monitored; consider an echocardiogram (ECHO) as clinically indicated.</p> <p>Cardiac assessment should then be repeated as clinically indicated or when starting new medication which affects the QT interval.</p> <p>Read more about <a href="#">cardiac toxicity associated with anti-cancer drugs</a></p>
<b>Pulmonary complications</b>	<p>Clinicians should evaluate patients for signs and symptoms of underlying cardiopulmonary disease before starting treatment and during treatment.</p> <p>Pleural effusions are dose dependent events and dose interruption, reduction or steroids should be considered. They are more common with dasatinib than with imatinib and may be bilateral or unilateral. Up to 35 % of patients treated with dasatinib on phase I/II studies developed pleural effusions, most often exudative.</p> <p>Pulmonary arterial hypertension (PAH) is an uncommon but serious complication. Echocardiogram is recommended in symptomatic patients (i.e. dyspnoea, cough, fatigue) and those with pleural effusions. Dasatinib should be withheld during evaluation if symptoms are severe, and permanently discontinued if PAH is confirmed i.e. not rechallenged.</p> <p>Pneumonitis and interstitial lung disease has also been reported.</p>
<b>Fluid retention/oedema</b>	<p>Dasatinib may cause severe fluid retention, including pleural and pericardial effusions, severe ascites, severe pulmonary oedema, and generalised oedema. This may be dose-related.</p> <p>Risk increases in patients greater than 65 years, patients with hypertension or prior cardiac history and those treated with twice daily dosing. (Note: once daily dosing is the recommended dosing schedule for all phases).</p> <p>Monitor regularly for signs and symptoms of fluid retention. Chest x-ray is recommended for symptoms suggestive of pleural effusion (eg. cough, dyspnoea).</p>
<b>Gastrointestinal toxicity</b>	<p>Diarrhoea is a common side effect of tyrosine kinase inhibitors (TKI) (e.g imatinib and dasatinib). If severe diarrhoea occurs, discontinue TKI until condition improves or resolves.</p> <p>Constipation has also been commonly reported with these regimens possibly related to the use of vinca alkaloids.</p> <p>Patients should be monitored closely, and prophylactic or symptom control anti-diarrhoeal/laxatives prescribed accordingly.</p>
<b>Efficacy of therapy</b>	<p>Measure efficacy of therapy using a standardised RT-PCR assay for BCR-ABL transcripts. Assess after the first cycle, at 2 to 4 month intervals while on hyper CVAD, and at 4 to 6 month intervals thereafter. Alternate therapies should be considered for patients who do not achieve a major molecular remission (defined as BCR-ABL less than 0.1% in the marrow) by 3 months and for those who lose their initial response on serial monitoring.</p>

<b>Corticosteroids</b>	<p>Diabetic patients should monitor their blood glucose levels closely. To minimise gastric irritation, advise patient to take immediately after food. Consider the use of a H2 antagonist or proton pump inhibitor if appropriate.</p> <p>Read more about <a href="#">acute short term effects from corticosteroids</a></p>
<b>Peripheral neuropathy</b>	<p>Assess prior to each treatment. Based on clinical findings, temporary omission, dose reduction or cessation of the vinca alkaloid may be indicated; review by medical officer before commencing treatment.</p> <p>Read more about <a href="#">peripheral neuropathy</a></p> <p>Link to <a href="#">chemotherapy-induced peripheral neuropathy screening tool</a></p>
<b>Pneumocystis jirovecii pneumonia (PJP) prophylaxis</b>	<p>PJP prophylaxis is recommended e.g. trimethoprim/sulfamethoxazole 160/800 mg PO one tablet twice daily, twice weekly (e.g. on Mondays and Thursdays) OR one tablet three times weekly (e.g. on Mondays, Wednesdays and Fridays).</p> <p>Read more about <a href="#">prophylaxis of pneumocystis jirovecii (carinii) in cancer patients</a></p>
<b>Antifungals and antivirals</b>	<p>There are no specific recommendations for the use of antifungal or antiviral prophylaxis with this treatment. The use of prophylaxis should be at the discretion of the treating clinician and based on patient risk factors and local guidelines.</p> <p>Read more about <a href="#">antifungal</a> and <a href="#">antiviral</a> prophylaxis</p>
<b>Blood tests</b>	<p>FBC, EUC, eGFR, LFTs, LDH, calcium, magnesium, phosphate, TSH and BSL at baseline. Consider weekly FBC for the first month of maintenance treatment. Repeat FBC prior to each cycle and EUC, eGFR, LFTs, LDH, calcium, magnesium, phosphate, TSH and BSL regularly throughout treatment as clinically indicated.</p>
<b>Hepatitis B screening and prophylaxis</b>	<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 <a href="#">hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy</a></p>
<b>Vaccinations</b>	<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 <a href="#">Australian Immunisation Handbook</a>.</p> <p>Read more about <a href="#">COVID-19 vaccines and cancer</a>.</p>
<b>Fertility, pregnancy and lactation</b>	<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. Pregnancy must be avoided while a female patient is on tyrosine kinase inhibitor (TKI) therapy. There are very few reports of pregnancy outcomes in partners of men receiving second or third-generation TKIs. Although the majority of infants fathered by men taking dasatinib were reported to be without congenital disabilities at birth, the general advice is for couples to avoid pregnancy (Carlier et al., 2017; Cortes et al., 2015). The safety of these drugs has not been proven, and therefore, pregnancy should be avoided. Effective contraception methods and adequate contraception timeframes 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 <a href="#">effect of cancer treatment on fertility</a>.</p> <p>Link to <a href="#">Carlier et al.</a> and <a href="#">Cortes et al.</a> references.</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
- All dasatinib dose modifications are taken directly from the dasatinib product information and should be considered at the discretion of the treating Haematologist

#### Haematological toxicity

##### Dasatinib starting dose 100 mg once daily

ANC less than $0.5 \times 10^9/L$ and/or platelets less than $10 \times 10^9/L$	<ol style="list-style-type: none"> <li>1. Stop dasatinib until <math>ANC \geq 1.0 \times 10^9/L</math> and platelets <math>\geq 50 \times 10^9/L</math></li> <li>2. Resume at the original starting dose of dasatinib</li> <li>3. If platelets <math>&lt; 25 \times 10^9/L</math> and/or recurrence of <math>ANC &lt; 50 \times 10^9/L</math> for <math>&gt; 7</math> days, repeat step 1 and resume at a reduced dose of 80 mg once daily for 2<sup>nd</sup> episode. For 3<sup>rd</sup> episode further reduce dose to 50 mg once daily (for newly diagnosed patients) or discontinue (patients resistant or intolerant to prior therapy including imatinib)</li> </ol>
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**Note:** The effects of dasatinib on platelet activation may also contribute to bleeding in addition to the thrombocytopenia

#### Renal impairment

Dasatinib and its metabolites are not significantly excreted via the kidney ( $<4\%$ ), therefore a decrease in total body clearance is not expected in renal insufficiency.

#### Hepatic impairment

Patients with mild, moderate or severe hepatic impairment may receive the recommended starting dose of dasatinib. However, dasatinib is metabolised extensively in the liver and caution is recommended.

#### Peripheral neuropathy

Grade 2 which is present at the start of the next cycle	Reduce vincristine by 50%
Grade 3 or Grade 4	Omit vincristine

#### Non-Haematological toxicity

Severe	Interrupt until resolved, then resume as appropriate at a reduced dose depending on the severity and recurrence of the event.
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## 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](#)

Dasatinib		
	Interaction	Clinical management
<b>H2 blockers (e.g. famotidine, ranitidine etc.) and Proton Pump Inhibitors (e.g.omeprazole, pantoprazole, rabeprazole etc.) and Antacids</b>	Reduced efficacy of dasatinib due to decreased absorption when gastric acid secretion suppressed (dasatinib requires acidic environment for absorption)	Avoid combination; acid neutralising antacids, e.g. Gastrogel®, Mylanta® (which have a shorter duration of action), may be used if separated from dasatinib administration by at least 2 hours
<b>CYP3A4 inhibitors (e.g. aprepitant, azole antifungals, clarithromycin, erythromycin, grapefruit juice, ritonavir etc.)</b>	Increased toxicity of dasatinib possible due to reduced clearance	Avoid combination or monitor for dasatinib toxicity and reduce the dose appropriately
<b>CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)</b>	Reduced efficacy of dasatinib possible due to increased clearance	Avoid combination or monitor for decreased clinical response to dasatinib
<b>Drugs metabolised by CYP3A4 (e.g. atorvastatin, benzodiazepines, calcineurin inhibitors, clarithromycin, dihydroergotamine, simvastatin, etc.)</b>	Increased effect/toxicity of these drugs possible due to inhibition of CYP3A4 by dasatinib resulting in reduced clearance	Avoid combination or monitor for increased effect/toxicity. (e.g. simvastatin exposure can be increased by 20%; heightening the risk of QT prolongation)
<b>Drugs that may prolong the QTc interval (e.g. azole antifungals, tricyclic antidepressants, antiarrhythmics etc.)</b>	Additive effect with dasatinib; may lead to torsades de pointes and cardiac arrest	Avoid combination or minimise additional risk factors (e.g. correct electrolyte imbalances) and monitor ECG for signs of cardiac arrhythmia
<b>Paracetamol</b>	Risk of liver toxicity due to inhibition of metabolism of paracetamol by dasatinib	Avoid combination or monitor liver function closely

Vincristine		
	Interaction	Clinical management
<b>CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin, grapefruit juice etc.)</b>	Increased toxicity of vincristine possible due to reduced clearance	Monitor for vincristine toxicity (esp. neurotoxicity, paralytic ileus)
<b>CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)</b>	Reduced efficacy of vincristine possible due to increased clearance	Monitor for decreased clinical response to vincristine
<b>Mitomycin</b>	Acute shortness of breath and severe bronchospasm has occurred following use of vincristine in patients who had received mitomycin simultaneously or within 2 weeks	Use combination with caution
<b>Ototoxic drugs (e.g. cisplatin, aminoglycosides, frusemide, NSAIDs)</b>	Additive ototoxicity	Avoid combination or perform regular audiometric testing

Prednisolone		
	Interaction	Clinical management
<b>Antidiabetic agents (e.g. insulin, glibenclamide, glicazide, metformin, pioglitazone, etc)</b>	The efficacy of antidiabetic agents may be decreased	Use with caution and monitor blood glucose
<b>Azole antifungals (e.g. fluconazole, itraconazole, ketoconazole, posaconazole)</b>	Increased toxicity of prednisolone possible due to reduced clearance	Avoid combination or monitor for prednisolone toxicity
<b>Oestrogens (e.g. oral contraceptives)</b>	Increased toxicity of prednisolone possible due to reduced clearance	Avoid combination or monitor for prednisolone toxicity. Dose reduction of prednisolone may be required
<b>Ritonavir</b>	Increased toxicity of prednisolone possible due to reduced clearance	Avoid combination or monitor for prednisolone toxicity

General		
	Interaction	Clinical management
<b>Warfarin</b>	Anti-cancer drugs may alter the anticoagulant effect of warfarin.	Monitor INR regularly and adjust warfarin dosage as appropriate; consider alternative anticoagulant.
<b>Direct oral anticoagulants (DOACs) e.g. apixaban, rivaroxaban, dabigatran</b>	<p>Interaction with both CYP3A4 and P-gp inhibitors /inducers.</p> <p>DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).</p>	<p>Apixaban: avoid concurrent use with strong <a href="#">CYP3A4</a> and <a href="#">P-gp</a> inhibitors. If treating VTE, avoid use with strong <a href="#">CYP3A4</a> and <a href="#">P-gp</a> inducers.</p> <p>Rivaroxaban: avoid concurrent use with strong <a href="#">CYP3A4</a> and <a href="#">P-gp</a> inhibitors.</p> <p>Dabigatran: avoid combination with strong <a href="#">P-gp</a> inducers and inhibitors.</p> <p>If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.</p>
<b>Digoxin</b>	Anti-cancer drugs can damage the lining of the intestine; affecting the absorption of digoxin.	Monitor digoxin serum levels; adjust digoxin dosage as appropriate.
<b>Antiepileptics</b>	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.
<b>Antiplatelet agents and NSAIDs</b>	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.
<b>Serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs e.g. paroxetine) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. venlafaxine)</b>	Increased risk of serotonin syndrome with concurrent use of 5-HT <sub>3</sub> receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	<p>Avoid combination.</p> <p>If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia). For more information link to <a href="#">TGA Medicines Safety Update</a></p>
<b>Vaccines</b>	Diminished response to vaccines and increased risk of infection with live vaccines.	<p>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.</p> <p>For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the <a href="#">Australian Immunisation Handbook</a></p>

## 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*



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## Day 1

**Approximate treatment time: 30 minutes**

[Safe handling and waste management](#)

[Safe administration](#)

[General patient assessment](#) prior to each day of treatment.

[Peripheral neuropathy assessment tool](#)

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

Prime IV line(s).

Insert IV cannula or access [TIVAD](#) or [CVAD](#).

- baseline weight

### Pre treatment medication

Verify antiemetics taken or administer as prescribed.

### 🕒 Treatment - Time out

#### Dasatinib

- administer orally ONCE a day
- to be swallowed whole with a glass of water; do not break, crush or chew
- may be taken with or without food.

**Note:** missed doses should not be replaced; if a dose is forgotten or vomited, normal dosing should be resumed at the next scheduled dose.

#### Prednisolone

- administer orally ONCE a day on **days 1 to 5**
- to be taken in the morning with or immediately after food

**Note:** if a dose is forgotten or vomited, contact treating team.

### 🕒 Chemotherapy - Time out

#### Vincristine

##### Administer vincristine (vesicant)

- via a minibag over 5 to 10 minutes
- ensure vein is patent and monitor for signs of extravasation throughout administration
- flush with ~150 mL of sodium chloride 0.9%.

Remove IV cannula and/or deaccess [TIVAD](#) or [CVAD](#).

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

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## Day 2 to 5

**This is an oral treatment**

[Safe handling and waste management](#) (reproductive risk only)

[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.

- weigh patient on each visit

### Pre treatment medication

Verify antiemetics taken or administer as prescribed.

### 🕒 Treatment - Time out

#### Dasatinib

- administer orally ONCE a day
- to be swallowed whole with a glass of water; do not break, crush or chew
- may be taken with or without food.

**Note:** missed doses should not be replaced; if a dose is forgotten or vomited, normal dosing should be resumed at the next scheduled dose.

#### Prednisolone

- administer orally ONCE a day on **days 1 to 5**
- to be taken in the morning with or immediately after food

**Note:** if a dose is forgotten or vomited, contact treating team.

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

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### Day 6 to 28

This is an oral treatment

[Safe handling and waste management](#) (reproductive risk only)

[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.

- weigh patient on each visit

### 🕒 Treatment - Time out

#### Dasatinib

- administer orally ONCE a day
- to be swallowed whole with a glass of water; do not break, crush or chew
- may be taken with or without food.

**Note:** missed doses should not be replaced; if a dose is forgotten or vomited, normal dosing should be resumed at the next scheduled dose.

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

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### Discharge information

#### Dasatinib tablets

- Dasatinib tablets with written instructions on how to take them.

#### Prednisolone tablets

- Prednisolone tablets with written instructions on how to take them.

#### Prophylaxis medications

- Prophylaxis medications (if prescribed) e.g. 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)

<b>Extravasation, tissue or vein injury</b>	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 <a href="#">extravasation management</a>
<b>Nausea and vomiting</b>	Read more about <a href="#">prevention of treatment induced nausea and vomiting</a>
<b>Taste and smell alteration</b>	Read more about <a href="#">taste and smell changes</a>

Early (onset days to weeks)	
<b>Neutropenia</b>	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 <a href="#">immediate management of neutropenic fever</a>
<b>Thrombocytopenia</b>	A reduction in the normal levels of functional platelets, increasing the risk of abnormal bleeding.  Read more about <a href="#">thrombocytopenia</a>
<b>Abdominal pain</b>	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.
<b>Cardiotoxicity</b>	Cardiotoxicity may manifest as asymptomatic reduction in left ventricular ejection fraction (LVEF), arrhythmia, cardiomyopathy, hypertension, cardiac ischaemia and congestive heart failure (CHF). The risk of cardiotoxicity is increased by a number of factors, particularly a history of heart disease and electrolyte imbalances. Read more about <a href="#">cardiotoxicity associated with anti-cancer drugs</a>
<b>Constipation</b>	
<b>Fatigue</b>	Read more about <a href="#">fatigue</a>
<b>Fluid retention and oedema</b>	An excess amount of fluid around the cells, tissues or serous cavities of the body, leading to swelling.
<b>Haemorrhage</b>	
<b>Hepatotoxicity</b>	Anti-cancer drugs administered either alone or in combination with other drugs and/or radiation may cause direct or indirect hepatotoxicity. Hepatic dysfunction can alter the metabolism of some drugs resulting in systemic toxicity.
<b>Oral mucositis</b>	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 <a href="#">oral mucositis</a>
<b>Ototoxicity</b>	Tinnitus and hearing loss may occur due to damage in the inner ear. Tinnitus is usually reversible, while hearing loss is generally irreversible. Hearing loss is dose-related, cumulative and may be worse in those with pre-existing hearing problems. Read more about <a href="#">ototoxicity - tinnitus and hearing loss</a>
<b>Peripheral neuropathy</b>	Typically symmetrical sensory neuropathy, affecting the fingers and toes, sometimes progressing to the hands and feet. It is associated with several classes of anti-cancer drugs. These include taxanes, platinum-based compounds, vinca alkaloids and some drugs used to treat multiple myeloma. Read more about <a href="#">peripheral neuropathy</a>
<b>Photosensitivity</b>	Increased sensitivity to ultraviolet (UV) light resulting in an exaggerated sunburn-like reaction accompanied by stinging sensations and urticaria.
<b>Side effects of corticosteroids</b>	Insomnia, oedema, increased risk of infection e.g. oral thrush, gastric irritation, worsening of peptic ulcer disease, increased blood sugar levels, loss of diabetic control, mood and behavioural changes - including anxiety, euphoria, depression, mood swings, increased appetite and weight gain, osteoporosis and fractures (long term use), bruising and skin fragility are associated with corticosteroid use.
<b>Skin rash</b>	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 <a href="#">skin rash</a>

Late (onset weeks to months)	
<b>Anaemia</b>	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood. Read more about <a href="#">anaemia</a>
<b>Alopecia - partial</b>	Hair thinning and/or patchy hair loss. Patients can also experience mild to moderate discomfort of the hair follicles, and rarely pain as the hair is falling out. Read more about <a href="#">alopecia</a> and <a href="#">scalp cooling</a>
<b>Cognitive changes (chemo fog)</b>	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 <a href="#">cognitive changes (chemo fog)</a>
<b>Depression</b>	
<b>Periorbital oedema</b>	Accumulation of fluid in the tissue surrounding the eye sockets (orbits).
Delayed (onset months to years)	
<b>Pulmonary toxicity</b>	Pulmonary toxicity may include damage to the lungs, airways, pleura and pulmonary circulation. Read more about <a href="#">pulmonary toxicity associated with anti-cancer drugs</a>

## Evidence

### Evidence

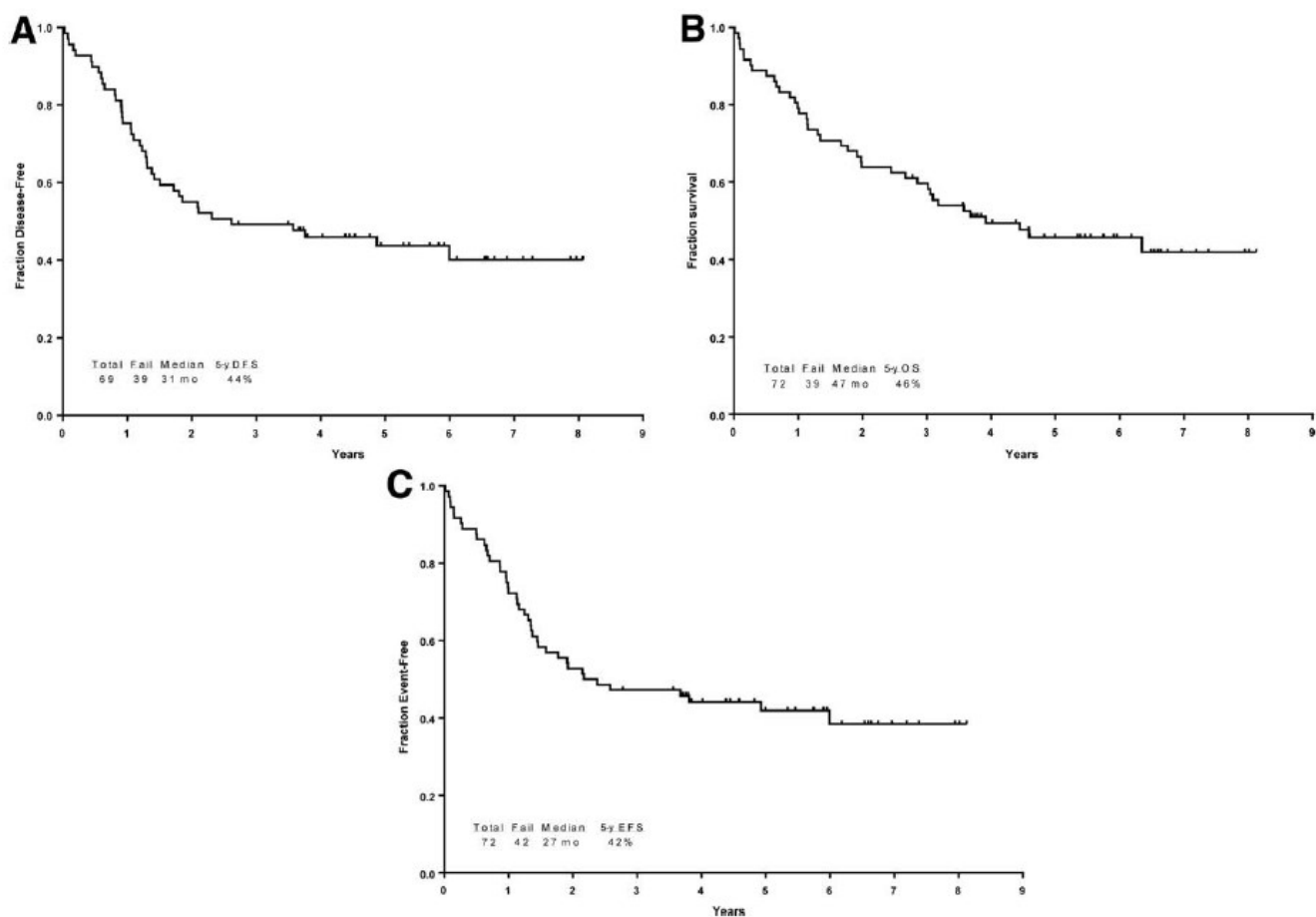
Dasatinib has significant clinical activity in patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to imatinib. Ravandi et al.<sup>1</sup> examined the efficacy and safety of combining hyper CVAD chemotherapy with dasatinib for 35 newly diagnosed patients with a median age of 53 (21-79). Dasatinib 50 mg twice a day or 100 mg once a day was given orally for the first 14 days of each 8 cycles of alternating hyper CVAD Part A and B. Patients who achieved complete remission (CR) were given maintenance of daily dasatinib and monthly vincristine and prednisone for 2 years, followed by dasatinib indefinitely. 94% of patients achieved CR, and a median disease-free survival (DFS) and median overall survival (OS) had not been reached at a median follow-up of 14 months, with an estimated 2-year survival of 64%.<sup>1</sup>

### Efficacy

A follow-up study confirmed long-term efficacy of the hyper CVAD chemotherapy in combination with dasatinib. 72 patients, median age 55 (21-80) with Ph+ ALL, either untreated or 1 or 2 prior cycles of therapy, were enrolled between 2006 and 2012. This study established dose equivalence between dasatinib 50 mg orally twice daily and dasatinib 100 mg daily and also further amended the protocol to give dasatinib 100 mg daily in the first 14 days of the first cycle, followed by 70 mg daily continuously from the second cycle. Maintenance with dasatinib, vincristine and prednisone was given monthly to patients who achieved CR for 2 years, followed by dasatinib indefinitely. Allogeneic stem cell transplant (SCT) was given in first complete remission (CR1) to eligible patients.<sup>2</sup>

69 patients (96%) achieved CR, of which 57 (83%) achieved cytogenetic (CG) CR after 1 cycle and 64 (93%) a major molecular response (MMR) at a median of 4 weeks (range, 2 – 38 weeks). At a median of 3 weeks (range, 2–37), minimal residual disease by flow cytometry was negative in 65 (94 %) patients. At a median follow-up of 67 months (range, 33–97), 33 patients (46%) were alive, and 30 (43%) in CR. 12 patients received an allogeneic SCT, and 39 patients died. The median DFS and OS was 31 months (range, 0.3 to 97) and 47 months (range, 0.2 to 97), respectively. Seven relapsed patients had ABL mutations, including 4 with T315I.<sup>2</sup>

**Figure 1: A) Disease-free survival, B) Overall survival and C) Event-free survival<sup>2</sup>**



**Figure 1.** (A) DFS, (B) OS, and (C) EFS for all patients. DFS indicates disease-free survival; EFS, event-free survival; OS, overall survival.

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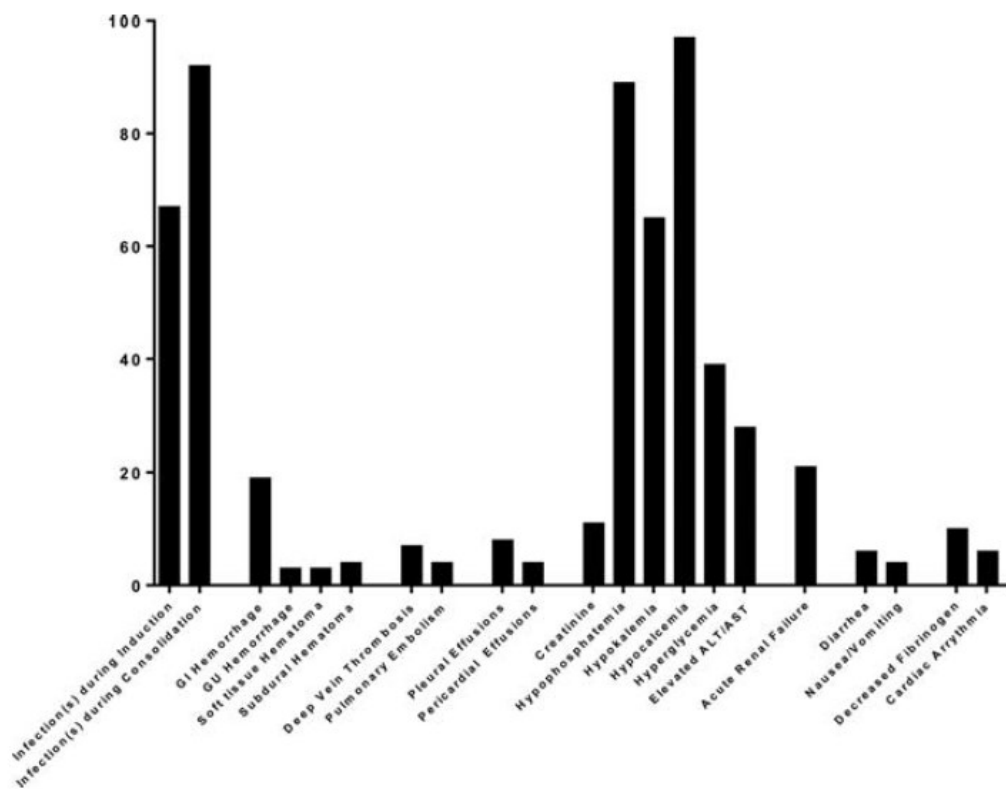
Furthermore, a multicentre trial found the addition of dasatinib in combination with chemotherapy followed by an allogeneic haematopoietic cell transplant (HCT) in patients with Ph+ ALL was feasible. Hyper CVAD + dasatinib treatment was administered, and of the 83 (88%) patients who achieved CR1, 41 patients received an allogeneic HCT where a donor was available, followed by daily dasatinib 100 mg starting from day 100. 33 patients actually received dasatinib post-HCT, and 30 (91%) of them required at least one dose reduction. Others received maintenance therapy with vincristine and prednisone for 2 years and dasatinib indefinitely. At median follow-up of 36 months (range, 9 - 63) for the overall cohort, overall survival (OS) was 69%, event-free survival (EFS) 55%, and relapse-free survival (RFS) 62%. The 12-month RFS was 71% and OS 87% after transplant.<sup>3</sup>

Source	Study & Year Published	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
Phase II trials	Ravandi et al. 2010 <sup>1</sup>	Yes	Yes	-
Phase II trials	Ravandi et al. 2015 <sup>2</sup>	Yes	Yes	-
Phase II trials	Ravandi et al. 2016 <sup>3</sup>	Yes	Yes	Hyper CVAD + dasatinib followed by allogeneic HCT
Guidelines	Date published/revised	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
NCCN	Acute lymphoblastic leukaemia Version 1, 2021	Yes	Yes	-
BCCA	N/A	N/A	N/A	-
CCO	N/A	N/A	N/A	-

Toxicity

Dasatinib was discontinued in 12 patients due to pleural effusions (n=6), pulmonary artery hypertension (n=2), gastrointestinal bleeding (n=2), skin cancer (n=1) and subdural bleeding (n=1).<sup>2</sup>

Figure 2: Dasatinib-related grade 3 and 4 adverse events included bleeding, pleural/pericardial effusions, and elevated transaminases.



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References

1 Ravandi, F., S. O'Brien, D. Thomas, et al. 2010. "First report of phase 2 study of dasatinib with hyper-CVAD for the frontline treatment of patients with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia." *Blood* 116(12):2070-2077.

2 Ravandi, F., S. M. O'Brien, J. E. Cortes, et al. 2015. "Long-term follow-up of a phase 2 study of chemotherapy plus dasatinib for the initial treatment of patients with Philadelphia chromosome-positive acute lymphoblastic leukemia." *Cancer* 121(23):4158-4164.

3 Ravandi, F., M. Othus, S. M. O'Brien, et al. 2016. "US Intergroup Study of Chemotherapy Plus Dasatinib and Allogeneic Stem Cell Transplant in Philadelphia Chromosome Positive ALL." *Blood Adv* 1(3):250-259.

History

Version 1

Date	Summary of changes
21/09/2018	New protocol proposed at Haematology Reference Committee meeting. Developed out of session (discussed electronically via email).
15/05/2019	Approved and published on eviQ V1. Review in 1 year.

Date	Summary of changes
05/08/2019	Drug status of dasatinib changed to reflect PBS update.
23/10/2020	Protocol reviewed electronically by Haematology Reference Committee, no changes. Review in 2 years.
21/12/2021	Changed antiemetic clinical information block to minimal or low, to align with new categories. See ID 7 Prevention of anti-cancer therapy induced nausea and vomiting (AINV) v5.
21/01/2022	Blood tests updated in clinical information. Pulmonary toxicity added to side effects.
25/07/2023	<ul style="list-style-type: none"> <li>Updated "Notes" in "Treatment schedule"</li> <li>Updated fertility information</li> <li>Reformatted evidence section</li> <li>Added "Extravasation, tissue or vein injury" to side effects.</li> </ul>

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](http://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/3532>

31 Jul 2023



# Patient information - Acute lymphoblastic leukaemia (ALL) - maintenance therapy (dasatinib, prednisolone and vincristine)



Patient's name:

## Your treatment

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


Maintenance therapy (dasatinib, prednisolone and vincristine)			
This treatment is started after you have finished treatment with hyper CVAD chemotherapy.			
This treatment cycle is repeated every 28 days and is ongoing for up to 2 years, dasatinib will then be continued as a single agent indefinitely.			
Day	Treatment	How it is given	How long it takes
1 to 28	<b>Dasatinib</b> ( <i>duh-sat-in-nib</i> )	Take orally ONCE a day with or without food and a large glass of water. Tablet(s) should be swallowed whole.	
1 to 5	<b>Prednisolone</b> ( <i>pred-NIS-oh-lone</i> )	Take orally ONCE in the morning with food on days 1 to 5.	
1	<b>Vincristine</b> ( <i>vin-KRIS-teen</i> )	By a drip into a vein	About 10 minutes

### Missed doses:

- **Dasatinib:** if you forget to take a tablet or vomit a tablet, take your normal dose the next time it is due. Do not take an extra dose.
- **Prednisolone:** if you forget to take your tablets or vomit your tablets, contact your treating team.

## 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.

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

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

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

## Other information about your treatment

### Changes to your dose or treatment delays

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

### Blood tests and monitoring

Anti-cancer drugs can reduce the number of blood cells in your body. You will need to have regular blood tests to check that your blood cell count has returned to normal. If your blood count is low, your treatment may be delayed until it has returned to normal. Your doctor or nurse will tell you when to have these blood tests.

### Central venous access devices (CVADs)

This treatment may involve 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.
- **Laxatives:** you may be given some medication to prevent or treat constipation. Your doctor or nurse will tell you how and when to take the laxatives.
- **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.

## 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)	
<b>Pain or swelling at injection site (extravasation)</b>	<ul style="list-style-type: none"><li>• This treatment can cause serious injury if it leaks from the area where it is going into the vein.</li><li>• This can cause pain, stinging, swelling or redness at or near the site where the drug enters the vein.</li><li>• If not treated correctly, you may get blistering and ulceration.</li><li>• <b>Tell your doctor or nurse immediately if you get any of the symptoms listed above during or after treatment.</b></li></ul>
<b>Nausea and vomiting</b>	<ul style="list-style-type: none"><li>• You may feel sick (nausea) or be sick (vomit).</li><li>• Take your anti-sickness medication as directed even if you don't feel sick.</li><li>• Drink plenty of fluids (unless you are fluid restricted).</li><li>• Eat small meals more frequently.</li><li>• Try food that does not require much preparation.</li><li>• Try bland foods like dry biscuits or toast.</li><li>• Gentle exercise may help with nausea.</li><li>• Ask your doctor or nurse for eviQ patient information - <a href="#">Nausea and vomiting during cancer treatment</a>.</li><li>• <b>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.</b></li></ul>
<b>Taste and smell changes</b>	<ul style="list-style-type: none"><li>• You may find that food loses its taste or tastes different.</li><li>• These changes are likely to go away with time.</li><li>• Do your mouth care regularly.</li><li>• Chew on sugar-free gum or eat sugar-free mints.</li><li>• Add flavour to your food with sauces and herbs.</li><li>• Ask your doctor or nurse for eviQ patient information - <a href="#">Taste and smell changes during cancer treatment</a>.</li></ul>
Early (onset days to weeks)	

<b>Infection risk (neutropenia)</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Wash your hands often.</li> <li>• Keep a thermometer at home and take your temperature regularly, and if you feel unwell.</li> <li>• Do your mouth care regularly.</li> <li>• Inspect your central line site (if you have one) daily for any redness, pus or swelling.</li> <li>• Limit contact with people who are sick.</li> <li>• Learn how to recognise the signs of infection.</li> <li>• Ask your doctor or nurse for eviQ patient information - <a href="#">Infection during cancer treatment</a>.</li> <li>• <b>Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:</b> <ul style="list-style-type: none"> <li>◦ a temperature of 38°C or higher</li> <li>◦ chills, shivers, sweats or shakes</li> <li>◦ a sore throat or cough</li> <li>◦ uncontrolled diarrhoea</li> <li>◦ shortness of breath</li> <li>◦ a fast heartbeat</li> <li>◦ become unwell even without a temperature.</li> </ul> </li> </ul>
<b>Low platelets (thrombocytopenia)</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Try not to bruise or cut yourself.</li> <li>• Avoid contact sport or vigorous exercise.</li> <li>• Clear your nose by blowing gently.</li> <li>• Avoid constipation.</li> <li>• Brush your teeth with a soft toothbrush.</li> <li>• Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to.</li> <li>• Tell your doctor or nurse if you have any bruising or bleeding.</li> <li>• <b>Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.</b></li> </ul>
<b>Stomach pain</b>	<ul style="list-style-type: none"> <li>• You may get: <ul style="list-style-type: none"> <li>◦ dull aches</li> <li>◦ cramping or pain</li> <li>◦ bloating or flatulence (gas).</li> </ul> </li> <li>• <b>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.</b></li> </ul>
<b>Heart problems</b>	<ul style="list-style-type: none"> <li>• You may get: <ul style="list-style-type: none"> <li>◦ chest pain or tightness</li> <li>◦ shortness of breath</li> <li>◦ swelling of your ankles</li> <li>◦ an abnormal heartbeat.</li> </ul> </li> <li>• Heart problems can occur months to years after treatment.</li> <li>• Tell your doctor if you have a history of heart problems or high blood pressure.</li> <li>• Before or during treatment, you may be asked to have a test to see how well your heart is working.</li> <li>• <b>Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the symptoms listed above.</b></li> </ul>

<b>Constipation</b>	<ul style="list-style-type: none"> <li>• You may have bowel motions (stools, poo) that are less frequent, harder, smaller, painful or difficult to pass.</li> <li>• You may also get: <ul style="list-style-type: none"> <li>◦ bloating, cramping or pain</li> <li>◦ a loss of appetite</li> <li>◦ nausea or vomiting.</li> </ul> </li> <li>• Drink plenty of fluids (unless you are fluid restricted).</li> <li>• Eat plenty of fibre-containing foods such as fruit, vegetables and bran.</li> <li>• Take laxatives as directed by your doctor.</li> <li>• Try some gentle exercise daily.</li> <li>• <b>Tell your doctor or nurse if you have not opened your bowels for more than 3 days.</b></li> </ul>
<b>Tiredness and lack of energy (fatigue)</b>	<ul style="list-style-type: none"> <li>• You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or things you enjoy.</li> <li>• Do not drive or operate machinery if you are feeling tired.</li> <li>• Nap for short periods (only 1 hour at a time)</li> <li>• Prioritise your tasks to ensure the best use of your energy.</li> <li>• Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted).</li> <li>• Try some gentle exercise daily.</li> <li>• Allow your friends and family to help.</li> <li>• <b>Tell your doctor or nurse if you get any of the symptoms listed above.</b></li> </ul>
<b>Extra fluid in the body (fluid retention)</b>	<ul style="list-style-type: none"> <li>• You may gain weight over a short amount of time.</li> <li>• Your hands and feet may become swollen, appear red or feel hot and uncomfortable.</li> <li>• Wear loose clothing and shoes that are not too tight.</li> <li>• Try not to stand up or walk around too much at one time.</li> <li>• If your ankles or legs get swollen, try raising them.</li> <li>• Make sure that any cuts or areas of broken skin are treated as soon as possible.</li> <li>• <b>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.</b></li> <li>• <b>Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you become short of breath.</b></li> </ul>
<b>Bleeding (haemorrhage)</b>	<ul style="list-style-type: none"> <li>• Tell your doctor or nurse if you have a wound that does not heal.</li> <li>• <b>Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:</b> <ul style="list-style-type: none"> <li>◦ <b>unusual bleeding or bruising</b></li> <li>◦ <b>bright red or black, tarry bowel motions (stools, poo)</b></li> <li>◦ <b>stomach pain</b></li> <li>◦ <b>slurred speech</b></li> <li>◦ <b>shortness of breath</b></li> <li>◦ <b>a fast heartbeat.</b></li> </ul> </li> </ul>
<b>Liver problems</b>	<ul style="list-style-type: none"> <li>• You may get: <ul style="list-style-type: none"> <li>◦ yellowing of your skin or eyes</li> <li>◦ itchy skin</li> <li>◦ pain or tenderness in your stomach</li> <li>◦ nausea and vomiting</li> <li>◦ loss of appetite</li> </ul> </li> <li>• You will have regular blood tests to check how well your liver is working.</li> <li>• <b>Tell your doctor or nurse as soon as possible if you notice that your urine is a dark colour, the whites of your eyes look yellow, or if you have stomach pain.</b></li> </ul>

<b>Mouth pain and soreness (mucositis)</b>	<ul style="list-style-type: none"> <li>You may have: <ul style="list-style-type: none"> <li>bleeding gums</li> <li>mouth ulcers</li> <li>a white coating on your tongue</li> <li>pain in the mouth or throat</li> <li>difficulty eating or swallowing.</li> </ul> </li> <li>Avoid spicy, acidic or crunchy foods and very hot or cold food and drinks.</li> <li>Try bland and soft foods.</li> <li>Brush your teeth gently with a soft toothbrush after each meal and at bedtime. If you normally floss continue to do so.</li> <li>Rinse your mouth after you eat and brush your teeth, using either: <ul style="list-style-type: none"> <li>1/4 teaspoon of salt in 1 cup of warm water, or</li> <li>1/4 teaspoon of bicarbonate of soda in 1 cup of warm water</li> </ul> </li> <li>Ask your doctor or nurse for eviQ patient information - <a href="#">Mouth problems during cancer treatment</a>.</li> <li><b>Tell your doctor or nurse if you get any of the symptoms listed above.</b></li> </ul>
<b>Hearing changes (ototoxicity)</b>	<ul style="list-style-type: none"> <li>You may get ringing in your ears or loss of hearing.</li> <li>You may have your hearing tested before and during your treatment.</li> <li><b>Tell your doctor or nurse as soon as possible if you notice any changes to your hearing.</b></li> </ul>
<b>Nerve damage (peripheral neuropathy)</b>	<ul style="list-style-type: none"> <li>You may notice a change in the sensations in your hands and feet, including: <ul style="list-style-type: none"> <li>tingling or pins and needles</li> <li>numbness or loss of feeling</li> <li>pain.</li> </ul> </li> <li>You may find it difficult to do everyday activities, such as doing up buttons or picking up small objects.</li> <li>Test water temperature with your elbow when bathing to avoid burns.</li> <li>Use rubber gloves, pot holders and oven mitts in the kitchen.</li> <li>Wear rubber shoes or boots when working in the garden or garage.</li> <li>Keep rooms well lit and uncluttered.</li> <li>Ask your doctor or nurse for eviQ patient information – <a href="#">Nerve problems during cancer treatment</a>.</li> <li>Tell your doctor or nurse if you get any of the symptoms listed above.</li> </ul>
<b>Skin that is more sensitive to the sun (photosensitivity)</b>	<ul style="list-style-type: none"> <li>After being out in the sun you may develop a rash like a bad sunburn.</li> <li>Your skin may become red, swollen and blistered.</li> <li>Avoid direct sunlight.</li> <li>Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and a sunscreen of SPF 50 or higher.</li> <li><b>Tell your doctor or nurse if you get any of the symptoms listed above.</b></li> </ul>
<b>Side effects from steroid medication</b>	<ul style="list-style-type: none"> <li>Steroid medication may cause: <ul style="list-style-type: none"> <li>mood swings and behaviour changes</li> <li>an increased appetite</li> <li>weight gain</li> <li>swelling in your hands and feet</li> <li>stomach upsets</li> <li>trouble sleeping</li> <li>fragile skin and bruising</li> <li>an increase in your blood sugar level</li> <li>weak and brittle bones (osteoporosis)</li> </ul> </li> <li>Take your steroid medication with food to reduce stomach upset</li> <li>If you have diabetes, your blood sugar levels may be tested more often.</li> <li>Tell your doctor or nurse if you get any of the symptoms listed above.</li> </ul>

<b>Skin rash</b>	<ul style="list-style-type: none"> <li>You may get a red, bumpy rash and dry, itchy skin.</li> <li>Moisturise your skin with a gentle non-perfumed moisturising cream like sorbolene or aqueous cream.</li> <li>Do not scratch your skin.</li> <li>Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and sunscreen of SPF 50 or higher.</li> <li><b>Talk to your doctor or nurse about other ways to manage your skin rash.</b></li> </ul>
<b>Late (onset weeks to months)</b>	
<b>Low red blood cells (anaemia)</b>	<ul style="list-style-type: none"> <li>You may feel dizzy, light-headed, tired and appear more pale than usual.</li> <li>Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion.</li> <li><b>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.</b></li> </ul>
<b>Hair thinning</b>	<ul style="list-style-type: none"> <li>Your hair may become dry and may break easily.</li> <li>You may lose some of your hair.</li> <li>Use a gentle shampoo and a soft hairbrush.</li> <li>Take care with hair products like hairspray, hair dye, bleaches and perms.</li> <li>Protect your scalp from the cold with a hat or scarf.</li> <li>Protect your scalp from the sun with a hat and sunscreen of SPF 50 or higher.</li> <li>Ask your doctor or nurse about the <a href="http://www.lgfb.org.au">Look Good Feel Better</a> program (www.lgfb.org.au)</li> </ul>
<b>Chemo brain (chemotherapy-related cognitive impairment)</b>	<ul style="list-style-type: none"> <li>You may notice that you are unable to concentrate, feel unusually disorganised or tired (lethargic) and have trouble with your memory.</li> <li>These symptoms usually improve once treatment is completed.</li> <li>Ask your doctor or nurse for eviQ patient information – <a href="#">Memory changes and chemotherapy (chemo brain)</a>.</li> <li>Tell your doctor or nurse if you get any of the symptoms listed above.</li> </ul>
<b>Depression</b>	<ul style="list-style-type: none"> <li>You may find that you: <ul style="list-style-type: none"> <li>have a low mood</li> <li>are tired</li> <li>don't have much energy</li> <li>lose interest in everyday activities</li> <li>have trouble concentrating or making decisions.</li> </ul> </li> <li>Keep a diary of how you are feeling once your treatment has started.</li> <li>Let your friends and family know how you are feeling.</li> <li>Tell your doctor or nurse if you get any of the signs or symptoms listed above.</li> </ul>
<b>Swelling around the eyes</b>	<ul style="list-style-type: none"> <li>You may get: <ul style="list-style-type: none"> <li>swelling or heaviness around your eyes</li> <li>irritated eyes</li> <li>eye discharge</li> <li>changes to your vision.</li> </ul> </li> <li><b>Tell your doctor or nurse if you get any of these symptoms.</b></li> </ul>

## Delayed (onset months to years)

### 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.
- Some pain medications, e.g. paracetamol, can interact with your treatment. Check with your doctor or pharmacist before taking any medications for a headache or mild pain.
- 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)

### Haematology, transplant and cellular therapy information

- Arrow bone marrow transplant foundation – [arrow.org.au](http://arrow.org.au)
- Australasian Menopause Society – [menopause.org.au](http://menopause.org.au)
- Chris O'Brien Lifehouse - Total Body Irradiation - [mylifehouse.org.au/departments/radiation-oncology/total-body-irradiation/](http://mylifehouse.org.au/departments/radiation-oncology/total-body-irradiation/)
- Healthy Male Andrology Australia – [healthymale.org.au/](http://healthymale.org.au/)
- International Myeloma Foundation – [myeloma.org](http://myeloma.org)
- Leukaemia Foundation – [leukaemia.org.au](http://leukaemia.org.au)
- Lymphoma Australia – [lymphoma.org.au](http://lymphoma.org.au)
- Myeloma Australia – [myeloma.org.au](http://myeloma.org.au)
- NSW Agency for Clinical Innovation, Blood & Marrow Transplant Network – [aci.health.nsw.gov.au/resources/blood-and-marrow-transplant](http://aci.health.nsw.gov.au/resources/blood-and-marrow-transplant)
- NSW Agency for Clinical Innovation - [aci.health.nsw.gov.au/projects/immune-effector-cell-service](http://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](http://nccn.org/patientresources/patient-resources/guidelines-for-patients)
- Talk Blood Cancer – [cmlsupport.org.uk/organisation-type/social-media-groups](http://cmlsupport.org.uk/organisation-type/social-media-groups)

### General cancer information and support

- Australian Rare Cancer (ARC) Portal – [arcportal.org.au/](http://arcportal.org.au/)
- Beyondblue – [beyondblue.org.au](http://beyondblue.org.au)
- Cancer Australia – [canceraustralia.gov.au](http://canceraustralia.gov.au)
- Cancer Council Australia – [cancer.org.au](http://cancer.org.au)
- Cancer Voices Australia – [cancervoicesaustralia.org](http://cancervoicesaustralia.org)
- CanTeen – [canteen.org.au](http://canteen.org.au)

- Carers Australia – [carersaustralia.com.au](http://carersaustralia.com.au)
- eviQ Cancer Treatments Online – [eviQ.org.au](http://eviQ.org.au)
- Food Standards Australia New Zealand: Listeria & Food Safety – [foodstandards.gov.au/publications/pages/listeriabrochuretext.aspx](http://foodstandards.gov.au/publications/pages/listeriabrochuretext.aspx)
- LGBTQI+ People and Cancer - [cancercouncil.com.au/cancer-information/lgbtqi](http://cancercouncil.com.au/cancer-information/lgbtqi)
- Look Good Feel Better – [lgfb.org.au](http://lgfb.org.au)
- Patient Information - [patients.cancer.nsw.gov.au](http://patients.cancer.nsw.gov.au)
- Radiation Oncology Targeting Cancer - [targetingcancer.com.au](http://targetingcancer.com.au)
- Redkite – [redkite.org.au](http://redkite.org.au)
- Return Unwanted Medicines – [returnmed.com.au](http://returnmed.com.au)
- Staying active during cancer treatment – [patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active](http://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](http://iCanQuit.com.au)
- Patient Information - [patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking](http://patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking)
- Quitnow – [quitnow.gov.au](http://quitnow.gov.au)

### Additional notes:

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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](http://www.eviQ.org.au)

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