

Breast metastatic trastuzumab emtansine

ID: 1598 v.4 Endorsed

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

The anticancer drug(s) in this protocol <u>may</u> 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 <u>eviQ Estimated Glomerular Filtration Rate (eGFR) calculator</u>.

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

,



Click here

Treatment schedule - Overview

Cycle 1 and further cycles

| Drug | Dose | Route | Day |
|-----------------------|-----------|-------------|-----|
| Trastuzumab emtansine | 3.6 mg/kg | IV infusion | 1 |

Frequency: 21 days

Cycles: Continuous until disease progression or unacceptable toxicity

Drug status: Trastuzumab emtansine (T-DM1) is PBS authority

Cost: ~ \$4,360 per cycle

Treatment schedule - Detail

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

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

Cycle 1 and further cycles

| Day 1 | | |
|-----------------------|-------------------------|--|
| Metoclopramide | 10 mg (PO) | one tablet when necessary (maximum of 30 mg/24 hours, up to 5 days) |
| Trastuzumab emtansine | 3.6 mg/kg (IV infusion) | in 250 mL sodium chloride 0.9% over 90 minutes (1st dose); if first dose is well tolerated, subsequent doses may be administered over 30 minutes |

Frequency: 21 days

Cycles: Continuous until disease progression or unacceptable toxicity

Breast metastatic trastuzumab emtansine Page 1 of 14

Indications and patient population

Indications:

- HER-2 positive metastatic (stage IV) breast cancer in patients whose disease has:
 - o progressed following treatment with trastuzumab (with or without pertuzumab) and a taxane for metastatic disease, or
 - o relapsed during or within six months of completing adjuvant therapy with trastuzumab and a taxane.

Cautions:

- left ventricular ejection fraction (LVEF) of 45% or less.
- · history of symptomatic congestive heart failure or serious cardiac arrhythmia requiring treatment.
- history of myocardial infarction or unstable angina within 6 months.
- pre-existing pulmonary disease; patients who experience dyspnoea at rest due to complications of advanced malignancy and comorbidities may be at an increased risk of pulmonary events and/or a fatal infusion reaction.
- pre-existing peripheral neuropathy of Grade 3 or greater.

| Clinical information | |
|--|---|
| Venous access required | IV cannula (IVC) or central venous access device (CVAD) is required to administer this treatment. Read more about central venous access device line selection |
| Hypersensitivity/infusion related reaction | Although hypersensitivity with trastuzumab emtansine is common, severe hypersensitivity reactions are uncommon. Use with caution in patients with dyspnoea at rest from pulmonary/cardiac conditions as increased risk of infusion related symptoms. Treatment with trastuzumab emtansine should be interrupted in patients with severe infusion related reactions (IRR) and permanently discontinued in the event of a life-threatening IRR. |
| Premedication | Premedication only required if patient has had a previous hypersensitivity reaction and should be based on clinical judgement. |
| Emetogenicity LOW | Suggested default antiemetics have been added to the treatment schedule, and may be substituted to reflect institutional policy. Ensure that patients also have sufficient antiemetics for breakthrough emesis: Metoclopramide 10 mg three times a day when necessary (maximum of 30 mg/24 hours, up to 5 days) OR Prochlorperazine 10 mg PO every 6 hours when necessary. Read more about preventing anti-cancer therapy induced nausea and vomiting |
| Cardiac toxicity associated with HER-2 directed agents | Patients receiving HER-2 directed agents are at an increased risk of cardiotoxicity e.g. asymptomatic decrease in the left ventricular ejection fraction (LVEF) and congestive heart failure (CHF). In patients with a LVEF less than 45% and/or symptomatic heart failure HER-2 directed therapy should be avoided, except in the metastatic setting when breast cancer is life-threatening and where a cardiologist is also involved. Concurrent anthracycline and HER-2 directed therapy is not recommended for extended periods of time. Baseline and 3 monthly cardiac function tests are required during treatment. In the metastatic setting, after the first 12 months of therapy, if there are no cardiac complications, the frequency of cardiac assessments may be reduced at the discretion of the treating clinician unless there has been recent exposure to anthracyclines. Read more about cardiac toxicity associated with HER-2 targeted agents |

| Hepatotoxicity | Trastuzumab emtansine has been associated with severe hepatotoxicity (including fatal outcomes). Monitor for abnormal liver function tests (LFTs), jaundice and tiredness. |
|---------------------------------------|---|
| | Nodular regenerative hyperplasia (NRH), leading to non-cirrhotic portal hypertension without LFT elevation, has also been observed in clinical trials. |
| | Dose reduction or treatment discontinuation may be required. Refer to dose modifications section below for specific recommendations. |
| Peripheral neuropathy | Assess prior to each treatment. If a patient experiences grade 2 or greater peripheral neuropathy, a dose reduction, delay, or omission of treatment may be required; review by medical officer before commencing treatment. |
| | Read more about peripheral neuropathy |
| | Link to chemotherapy-induced peripheral neuropathy screening tool |
| Pulmonary toxicity | Interstitial Lung Disease (ILD), including pneumonitis, sometimes leading to acute respiratory distress syndrome or fatality, has been reported in patients treated with trastuzumab emtansine. Treatment should be permanently discontinued in patients diagnosed with ILD or pneumonitis. |
| Thrombocytopenia | In clinical trials, thrombocytopenia was reported in ~ 30% of patients treated with T-DM1 with a higher incidence and severity reported in Asian patients. Severe cases of haemorrhagic events, including fatal outcomes, have been observed. |
| | Patients with thrombocytopenia or who are on anti-coagulant treatment should be monitored closely. |
| Blood tests | FBC, EUC and LFTs at baseline and prior to each treatment. |
| Hepatitis B screening and prophylaxis | Routine screening for HBsAg and anti-HBc is NOT usually recommended for patients receiving this treatment. |
| | Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy |
| Vaccinations | Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease. |
| | Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook. |
| | Read more about COVID-19 vaccines and cancer. |
| Fertility, pregnancy and lactation | Cancer treatment can have harmful effects on fertility and this should be discussed with all patients of reproductive potential prior to commencing treatment. There is a risk of foetal harm in pregnant women. A pregnancy test should be considered prior to initiating treatment in females of reproductive potential if sexually active. It is important that all patients of reproductive potential use effective contraception whilst on therapy and after treatment finishes. Effective contraception methods and adequate contraception timeframe should be discussed with all patients of reproductive potential. Possibility of infant risk should be discussed with breastfeeding patients. |
| | Read more about the effect of cancer treatment on fertility |

Dose modifications

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

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

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

Note:

- Dose reductions should be made in decrements of 0.6 mg/kg.
- A maximum of 2 dose reductions should occur before discontinuation.
- The dose should not be re-escalated after a dose reduction has been made.
- Haematological dose modifications have been adapted from the product information.

| Haematological toxicity | | |
|---|---|--|
| Platelets x 10 ⁹ /L (pre-treatment blood test) | | |
| 25 to less than 50 | Delay treatment until recovery (platelets $75 \times 10^9/L$ or greater) then resume trastuzumab emtansine at the same dose | |
| less than 25 | Delay treatment until recovery and restart trastuzumab emtansine as follows: 1st occurrence: Restart trastuzumab emtansine at 3 mg/kg 2nd occurrence: Restart trastuzumab emtansine at 2.4 mg/kg 3rd occurrence: Cease trastuzumab emtansine | |

| Renal impairment | |
|------------------|--|
| Mild to moderate | No dose modifications necessary |
| Severe | Insufficient data in patients with severe renal impairment |

| Hepatic impairment | | | |
|--|---|--|--|
| Pre-existing hepatic dysfunction | | | |
| Mild to moderate | No dose modifications necessary | | |
| Severe | Not recommended as it has not been studied in patients with severe hepatic impairment | | |
| Trastuzumab emtansine induced hep | patotoxicity | | |
| Increased Serum Transaminases (AL | T / AST) | | |
| ALT / AST from greater than 2.5 x ULN to 5 x ULN | Continue treatment with trastuzumab emtansine at the same dose | | |
| ALT / AST from greater than 5 x ULN to 20 x ULN | Delay treatment until ALT / AST is 5 x ULN or less and restart trastuzumab emtansine as follows: 1st occurrence: Restart trastuzumab emtansine at 3 mg/kg 2nd occurrence: Restart trastuzumab emtansine at 2.4 mg/kg 3rd occurrence: Cease trastuzumab emtansine | | |
| ALT / AST greater than 20 x ULN | Permanently discontinue trastuzumab emtansine | | |
| Hyperbilirubinaemia | | | |
| Bilirubin from greater than 1.5 x ULN to 3 x ULN | Delay treatment until bilirubin is 1.5 x ULN or less, then resume treatment with trastuzumab emtansine at the same dose | | |
| Bilirubin from greater than 3 x ULN to 10 x ULN | Delay treatment until Bilirubin is 1.5 x ULN or less and restart trastuzumab emtansine as follows: 1st occurrence: Restart trastuzumab emtansine at 3 mg/kg 2nd occurrence: Restart trastuzumab emtansine at 2.4 mg/kg 3rd occurrence: Cease trastuzumab emtansine | | |
| Bilirubin greater than 10 x ULN | Permanently discontinue trastuzumab emtansine | | |

| Hepatic impairment | | |
|---|---|--|
| Increased Serum Transaminases (ALT / AST) with Hyperbilirubinaemia | | |
| ALT / AST greater than 3 x ULN and Bilirubin greater than 2 x ULN | Permanently discontinue trastuzumab emtansine | |
| Nodular Regenerative Hyperplasia (NRH) | | |
| Clinical symptoms of portal hypertension and/or cirrhosis-like computed tomography (CT) picture without LFT elevation or other signs of cirrhosis | Permanently discontinue trastuzumab emtansine | |

| Peripheral neuropathy | |
|-----------------------|--|
| Grade 3 or Grade 4 | Temporarily discontinue trastuzumab emtansine until symptoms resolve or improve to Grade 2 or less and continue to monitor |

| Cardiac toxicity | | |
|---|---|--|
| Consider referral to a cardiologist if any of the following occur | | |
| LVEF 40% to 45% AND/OR 10% point <i>or</i> greater decline from baseline Delay trastuzumab emtansine, repeat LVEF assessment within 3 weeks Discontinue treatment if LVEF has not recovered to within 10% points of baseline | | |
| LVEF less than 40% | Delay trastuzumab emtansine, repeat LVEF assessment within 3 weeks Discontinue treatment if LVEF less than 40% is confirmed | |
| Symptomatic Congestive Heart Failure (CHF) Discontinue trastuzumab emtansine | | |

| Interstitial lung disease (ILD)/ <u>pneumonitis</u> | |
|---|---|
| Any grade | Permanently discontinue trastuzumab emtansine |

Missed doses of trastuzumab emtansine

If a planned dose is delayed or missed, administer as soon as possible at the most recently tolerated infusion rate; do not wait until the next planned cycle

Following a delayed or missed dose, adjust administration schedule to maintain a 3 week dosing interval.

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

| Trastuzumab Emtansine | | |
|--|---|--|
| | Interaction | Clinical management |
| CYP3A4 inhibitors (e.g. aprepitant, azole antifungals, clarithromycin, erythromycin, grapefruit juice, ritonavir etc.) | Increased toxicity of DM1, the cytotoxic component of trastuzumab emtansine, possible due to reduced clearance | Avoid combination or monitor for trastuzumab emtansine toxicity |
| CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.) | Reduced efficacy of trastuzumab emtansine possible due to increased clearance of DM1, the cytotoxic component of trastuzumab emtansine | Avoid combination or monitor for decreased clinical response to trastuzumab emtansine |
| Cardiotoxic drugs (e.g. anthracyclines cyclophosphamide) | Additive cardiotoxicity | Monitor cardiac function closely in patients who have previously been treated with cumulatively cardiotoxic drugs |
| Paclitaxel | Increased toxicity of trastuzumab emtansine possible due to reduced clearance | Avoid combination or minimise additional risk factors (e.g. correct electrolyte imbalances) and monitor ECG for signs of cardiac arrhythmia |

| 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

Day 1

Approximate treatment time: 2 hours (initial); 1 hour (subsequent)

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) with sodium chloride 0.9%.

Insert IV cannula or access TIVAD or CVAD.

Pre treatment medication

Administer antiemetics if required

Ochemotherapy - Time out

Trastuzumab emtansine

- Trastuzumab emtansine is incompatible with glucose solutions.
- If sodium chloride 0.9% is used for the infusion, a 0.22 micron in-line polyethersulfone (PES) filter is required.

Initial infusion - administer trastuzumab emtansine (irritant):

- via IV infusion over 90 minutes
- flush with ~50 mL of sodium chloride 0.9%
- observe patient for hypersensitivity reaction throughout administration and for ~ 90 minutes following completion
- 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
 - o for severe reactions seek medical assistance immediately and do not restart infusion
- educate the patient about the possibility of delayed infusion-related symptoms.

Subsequent infusions - administer trastuzumab emtansine (irritant):

- if no previous hypersensitivity reaction administer via IV infusion over 30 minutes
- flush with ~50 mL of sodium chloride 0.9%
- observe patient for hypersensitivity reaction throughout administration and for at least 30 minutes after completion of subsequent infusions
- 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
 - o for severe reactions seek medical assistance immediately and do not restart infusion
- educate the patient about the possibility of delayed infusion-related symptoms.

Remove IV cannula and/or deaccess TIVAD or CVAD.

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

Discharge information

Antiemetics

· Antiemetics as prescribed.

Patient information

• Ensure patient receives patient information sheet.

Side effects

The side effects listed below are not a complete list of all possible side effects for this treatment. Side effects are categorised into the approximate onset of presentation and should only be used as a guide.

| Immediate (onset hours to days) | | |
|--|---|--|
| 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 | | |
| Hypersensitivity reaction Anaphylaxis and infusion related reactions can occur with this treatment. Read more about hypersensitivity reaction | | |
| Nausea and vomiting | Read more about prevention of treatment induced nausea and vomiting | |
| Taste and smell alteration | Iteration Read more about taste and smell changes | |

| 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. |
| Haemorrhage | Read more about thrombocytopenia |
| Oral mucositis | Erythematous and ulcerative lesions of the gastrointestinal tract (GIT). It commonly develops following chemotherapy, radiation therapy to the head, neck or oesophagus, and high dose chemotherapy followed by a blood and marrow transplant (BMT). |
| | Read more about oral mucositis |
| Constipation | |
| Diarrhoea | Read more about treatment induced diarrhoea |
| Fatigue | Read more about fatigue |
| Arthralgia and myalgia | Generalised joint pain or and/or stiffness and muscle aches, often worse upon waking or after long periods of inactivity. Can improve with movement. May be mild or severe, intermittent or constant and accompanied by inflammation. |
| | Read more about arthralgia and myalgia |
| Hypokalaemia | Abnormally low levels of potassium in the blood. |
| Hepatotoxicity | 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. |
| Epistaxis | Acute bleeding from the nostril(s), nasal cavity, or nasopharynx. |
| Palmar-plantar erythrodysaesthesia (PPE) - hand-foot syndrome (HFS) | Bilateral erythema, tenderness, pain, swelling, tingling, numbness, pruritus, dry rash, or moist desquamation and ulceration of the palms and soles. It is also known as hand-foot syndrome (HFS). Symptoms appear to be dose dependent and palms are affected more than soles. Read more about hand-foot syndrome associated with chemotherapy |
| Skin rash | Anti-cancer drugs can cause a number of changes in the skin with maculo-papular rash the most common type of drug-induced skin reaction. Read more about skin rash |
| Peripheral neuropathy | Typically symmetrical sensory neuropathy, affecting the fingers and toes, sometimes progressing to the hands and feet. It is associated with several classes of anti-cancer drugs. These include taxanes, platinum-based compounds, vinca alkaloids and some drugs used to treat multiple myeloma. Read more about peripheral neuropathy |
| Ocular changes | Symptoms may include eye pain, blurred vision, blepharitis, uveitis, optic neuritis, tear duct stenosis, conjunctivitis, hyperlacrimation, watery or dry eyes and photophobia. |

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

Delayed (onset months to years)

Cardiotoxicity

Cardiotoxicity is a well recognised complication of HER-2 directed agents (e.g. trastuzumab, trastuzumab emtansine, pertuzumab). Mechanistically distinct from anthracycline-induced cardiotoxicity, it typically manifests as an asymptomatic decrease in the left ventricular ejection fraction (LVEF) and less commonly as congestive heart failure (CHF).

Read more about cardiac toxicity associated with HER-2 targeted agents

Evidence

The evidence supporting this protocol is provided by a phase 3, multicentre, international, randomised trial - EMILIA, involving 991 patients, comparing the efficacy and safety of trastuzumab emtansine (T-DM1) with lapatinib plus capecitabine (standard of care) in patients with HER2-positive, unresectable, locally advanced or metastatic breast cancer, who received prior therapy with trastuzumab and a taxane and whose disease has progressed despite treatment with trastuzumab for metastatic disease, or within 6 months of completing adjuvant therapy.¹

Between February 2009 and October 2011, a total of 991 patients were enrolled:

- 496 patients (control) were assigned to receive oral lapatinib 1250 mg daily, plus oral capecitabine 1000 mg/m² BD (maximum 2000 mg/m²/day) on days 1 through 14 of each 21-day treatment cycle
- 495 patients were assigned to receive trastuzumab emtansine (T-DM1) 3.6 mg/kg intravenously every 21 days

Both groups of patients continued to receive the study treatment until disease progression (investigator-assessed) or the development of unmanageable toxic effects.¹

The primary end points were progression-free survival assessed by independent review, overall survival, and safety. Pre-specified secondary end points included progression-free survival (investigator-assessed), the objective response rate, the duration of response, and the time to symptom progression.¹

In a separate study comparing trastuzumab emtansine and physician's choice as 3rd-line treatment for metastatic breast cancer, trastuzumab emtansine showed a 3-month progression-free survival benefit over physician's choice in this patient population (hazard ratio, HR 0.258 (0.422-0.661); p < 0.0001).²

Efficacy

After a median follow up of 13 months, PFS was 9.6 months with T-DM1, vs. 6.4 months with lapatinib plus capecitabine (stratified hazard ratio for progression or death from any cause, 0.65; 95% CI, 0.55 to 0.77; p<0.001).

At the first interim analysis of overall survival (223 deaths), the stratified hazard ratio for death from any cause with T-DM1 vs. lapatinib plus capecitabine was 0.62 (95% CI, 0.48 to 0.81; p=0.0005) and did not cross the predefined O'Brien-Fleming stopping boundary (p=0.0003). At the second interim analysis of overall survival (331 deaths), T-DM1 significantly increased median overall survival (30.9 months, vs. 25.1 months with lapatinib plus capecitabine; hazard ratio for death from any cause, 0.68; 95% CI, 0.55 to 0.85; p<0.001). At the final descriptive analysis, median overall survival was 29.9 months (95% CI 26.3 to 34.1) with T-DM1 vs. 25.9 months (95% CI 22.7 to 28.3) with lapatinib plus capecitabine; hazard ratio 0.75 (95% CI, 0.64 to 0.88).

Progression-free survival (assessed by an independent review committee)¹

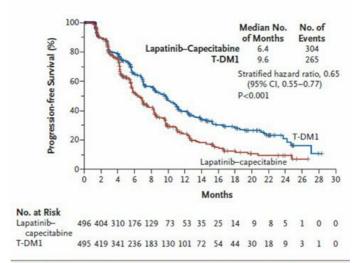
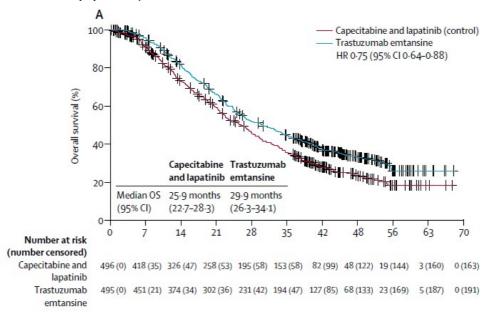


Figure 1. Progression-free Survival, as Assessed by an Independent Review

Shown are Kaplan–Meier estimates of progression-free survival in the intention-to-treat population, stratified according to world region, number of prior chemotherapy regimens (0 or 1 vs. >1), and site of disease involvement (visceral vs. nonvisceral). Median progression-free survival was 3.2 months longer in the trastuzumab emtansine (T-DM1) group than in the lapatinib—capecitabine group. CI denotes confidence interval.

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Overall survival (intention-to-treat population)³



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Objective-response rate and duration of response (assessed by an independent review committee)¹

| Variable | Lapatinib plus Capecitabine (N=389) | T-DM1 (N=397) | Difference | P Value |
|---|-------------------------------------|------------------|-----------------|---------|
| Complete or partial response | | | | |
| No. of patients | 120 | 173 | | |
| Percent (95% CI) | 30.8 (26.3-35.7) | 43.6 (38.6-48.6) | 12.7 (6.0-19.4) | < 0.001 |
| Complete response — no. (%) | 2 (0.5) | 4 (1.0) | | |
| Partial response — no. (%) | 118 (30.3) | 169 (42.6) | | |
| Duration of complete or partial response — mo | | | | |
| Median | 6.5 | 12.6 | | |
| 95% CI | 5.5-7.2 | 8.4-20.8 | | |

^{*} The total number of patients in each group is the number with measurable disease at baseline, as determined by independent review. CI denotes confidence interval.

Overall, T-DM1 has a better toxicity profile and greater efficacy than lapatinib with capecitabine for 1st line (fast-relapsing) and 2nd line treatment of HER2-positive metastatic breast cancer in patients who previously received trastuzumab and a taxane.

Toxicitu

T-DM1 regimen is less toxic than lapatinib and capecitabine. Serious adverse events in the safety population were reported in 18% of the patients in the lapatinib—capecitabine group vs. 15.5% in the T-DM1 group.¹

The incidence rates of adverse events of grade 3 or above were higher in the lapatinib—capecitabine group than in the T-DM1 group (57.0% vs. 40.8%). Diarrhoea and palmar—plantar erythrodysesthesia were the most commonly reported grade 3 or 4 events in the lapatinib—capecitabine group, affecting 20.7% and 16.4% of patients, respectively. The most commonly reported grade 3 or 4 events with T-DM1 were thrombocytopenia (12.9%) and elevated serum concentrations of aspartate aminotransferase (AST) (4.3%) and alanine aminotransferase (ALT) (2.9%).

For most patients, the first occurrence of grade 3 or 4 thrombocytopenia was reported during the first two cycles of T-DM1 treatment; with dose modifications, the majority of these patients were able to continue treatment (10 patients [2.0%] discontinued T-DM1 because of thrombocytopenia).

The overall incidence of bleeding events was higher with T-DM1 (29.8%, vs. 15.8% with lapatinib plus capecitabine); rates of grade 3 or 4 bleeding events were low in both groups (1.4% and 0.8%, respectively).¹

In the majority of patients, a left ventricular ejection fraction of 45% or more was maintained during the study treatment (in 97.1% of patients in the T-DM1 group and 93.0% of patients in the lapatinib—capecitabine group). Three patients in each group had a decrease from baseline to less than 40%. 1.7% of patients in the T-DM1 group and 1.6% of patients in the lapatinib—capecitabine group had an ejection fraction that was less than 50% and at least 15 percentage points below the baseline value.¹

96.1% and 96.8% of deaths occurring during the study period were attributed to disease progression in the lapatinib—capecitabine group and T-DM1 group respectively. Five deaths were attributed to adverse events that occurred within 30 days after the last dose of a study drug: 4 deaths in the lapatinib—capecitabine group (due to coronary artery disease, multi-organ failure, coma, and hydrocephalus) and 1 death in the T-DM1 group (due to metabolic encephalopathy after CNS progression).¹

Adverse events¹

| Adverse Event | Lapatinib plus Capecitabine (N = 488) | | T-DM1 (N = 490) | | |
|-----------------------------------|---------------------------------------|-------------------------------|------------------------|-------------------|--|
| | Events of Any Grade | Events of Grade 3 or Above | Events of Any Grade | Events of Grade 3 | |
| | number of patients (percent) | | | | |
| Any event | 477 (97.7) | 278 (57.0) | 470 (95.9) | 200 (40.8) | |
| Specific events† | | | | () | |
| Diarrhea | 389 (79.7) | 101 (20.7) | 114 (23.3) | 8 (1.6) | |
| Palmar-plantar erythrodysesthesia | 283 (58.0) | 80 (16.4) | 6 (1.2) | 0 | |
| Vomiting | 143 (29.3) | 22 (4.5) | 93 (19.0) | 4 (0.8) | |
| Neutropenia | 42 (8.6) | 21 (4.3) | 29 (5.9) | 10 (2.0) | |
| Hypokalemia | 42 (8.6) | 20 (4.1) | 42 (8.6) | 11 (2.2) | |
| Fatigue | 136 (27.9) | 17 (3.5) | 172 (35.1) | 12 (2.4) | |
| Nausea | 218 (44.7) | 12 (2.5) | 192 (39.2) | 4 (0.8) | |
| Mucosal inflammation | 93 (19.1) | 11 (2.3) | 33 (6.7) | 1 (0.2) | |
| Anemia | 39 (8.0) | 8 (1.6) | 51 (10.4) | 13 (2.7) | |
| Elevated ALT | 43 (8.8) | 7 (1.4) | 83 (16.9) | 14 (2.9) | |
| Elevated AST | 46 (9.4) | 4 (0.8) | 110 (22.4) | 21 (4.3) | |
| Thrombocytopenia | 12 (2.5) | 1 (0.2) | 137 (28.0) | 63 (12.9) | |

^{*} The safety population included all patients who received at least one dose of the study treatment. ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.

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References

1 Verma, S., D. Miles, L. Gianni, et al. 2012. "Trastuzumab emtansine for HER2-positive advanced breast cancer." N Engl J Med 367(19):1783-1791.

[†] Listed are adverse events of grade 3 or above with an incidence of 2% or higher in either group.

- **2** Krop, I. E., S. B. Kim, A. Gonzalez-Martin, et al. 2014. "Trastuzumab emtansine versus treatment of physician's choice for pretreated HER2-positive advanced breast cancer (TH3RESA): a randomised, open-label, phase 3 trial." Lancet Oncol.
- 3 Dieras, V., D. Miles, S. Verma, et al. 2017. "Trastuzumab emtansine versus capecitabine plus lapatinib in patients with previously treated HER2-positive advanced breast cancer (EMILIA): a descriptive analysis of final overall survival results from a randomised, open-label, phase 3 trial." Lancet Oncol 18(6):732-742.

History

Version 4

| Date | Summary of changes |
|------------|--|
| 27/04/2021 | Dose modifications updated to include ILD/pneumonitis, pre-existing hepatic dysfunction updated to align with product information. Constipation added to side effects. Protocol and patient information administration times updated. Version number changed to V.4. |

Version 3

| Date | Summary of changes |
|------------|---|
| 09/05/2014 | New protocol taken to Medical Oncology Reference Committee meeting. |
| 16/06/2014 | Approved and published on eviQ. |
| 01/07/2015 | Protocol reviewed electronically by Medical Oncology Reference committee. No changes and next review in 1 year. |
| 22/09/2015 | Cardiac toxicity monitoring updated. |
| 08/04/2016 | Protocol reviewed at Medical Oncology Reference Committee meeting. No changes and next review in 2 years. |
| 31/05/2017 | Transferred to new eviQ website. Version number change to V.2. Hepatitis B screening changed to NOT recommended. |
| 20/02/2019 | Protocol reviewed electronically by Medical Oncology Reference Committee. Evidence section updated to include final overall survival data. Treatment schedule updated to include first and subsequent infusion times in the same section. Version number change to V.3. Next review in 5 years. |

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

First approved: 16 June 2014
Last reviewed: 20 February 2019
Review due: 31 December 2023

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/1598

08 Jun 2023

Patient information - Breast cancer metastatic - Trastuzumab emtansine



Patient's name:

Your treatment

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

| Trastuzumab emtansine | | | | | |
|--|--|-----------------------|--|--|--|
| This treatment cycle is repeated every 21 days. Your doctor will advise you of the number of treatments you will have. | | | | | |
| Day | Treatment How it is given How long it takes | | | | |
| 1 | Trastuzumab emtansine (tras-T00Z-ue-mab em-taan-zine) | By a drip into a vein | About 2 hours for the first treatment. If no reactions, subsequent treatment may be given over a shorter amount of time e.g. 1 hour. | | |

When to get help

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

| IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you have any of the following at any time: | Emergency contact details Ask your doctor or nurse from your treating team who to contact if you have a problem |
|---|--|
| a temperature of 38°C or higher chills, sweats, shivers or shakes shortness of breath uncontrolled vomiting or diarrhoea pain, tingling or discomfort in your chest or arms you become unwell. | Daytime: Night/weekend: Other instructions: |

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

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

Other information about your treatment

Changes to your dose or treatment delays

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

treatment. This is called a dose reduction, dose change or treatment delay. Your doctor will explain if you need any changes or delays to your treatment and the reason why.

Blood tests and monitoring

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

Other medications given during this treatment

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

Side effects

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

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

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

Immediate (onset hours to days) • This treatment can cause serious injury if it leaks from the area where it is going into the Pain or swelling at injection site (extravasation) • 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. • Allergic reactions are uncommon but can be life threatening. **Allergic reaction** • If you feel unwell during the infusion or shortly after it, or: o 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 While you are in hospital: Tell your doctor or nurse immediately. After you leave: Contact your doctor or nurse immediately, or go to the nearest hospital **Emergency Department.** • You may feel sick (nausea) or be sick (vomit). Nausea and vomiting • 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. • You may find that food loses its taste or tastes different. Taste and smell changes 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.

Early (onset days to weeks)

Infection risk (neutropenia)

- This treatment lowers the amount of white blood cells in your body. The type of white blood
 cells that help to fight infection are called neutrophils. Having low level of neutrophils is
 called neutropenia. If you have neutropenia, you are at greater risk of getting an infection. It
 also means that your body can't fight infections as well as usual. This is a serious side effect,
 and can be life threatening.
- · Wash your hands often.
- Keep a thermometer at home and take your temperature regularly, and if you feel unwell.
- Do your mouth care regularly.
- Inspect your central line site (if you have one) daily for any redness, pus or swelling.
- · Limit contact with people who are sick.
- Learn how to recognise the signs of infection.
- Ask your doctor or nurse for eviQ patient information Infection during cancer treatment.
- Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:
 - a temperature of 38°C or higher
 - o chills, shivers, sweats or shakes
 - o a sore throat or cough
 - uncontrolled diarrhoea
 - shortness of breath
 - o a fast heartbeat
 - become unwell even without a temperature.

Low platelets (thrombocytopenia)

- This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising.
- · Try not to bruise or cut yourself.
- Avoid contact sport or vigorous exercise.
- Clear your nose by blowing gently.
- · Avoid constipation.
- Brush your teeth with a soft toothbrush.
- Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to.
- Tell your doctor or nurse if you have any bruising or bleeding.
- Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.

Bleeding (haemorrhage)

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

· You may have: Mouth pain and soreness o bleeding gums (mucositis) mouth ulcers a white coating on your tongue o 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: o 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. • You may have bowel motions (stools, poo) that are less frequent, harder, smaller, painful or Constipation difficult to pass. • You may also get: bloating, cramping or pain a loss of appetite o nausea or vomiting. • Drink plenty of fluids (unless you are fluid restricted). Eat plenty of fibre-containing foods such as fruit, vegetables and bran. • Take laxatives as directed by your doctor. • Try some gentle exercise daily. • Tell your doctor or nurse if you have not opened your bowels for more than 3 days. • You may get bowel motions (stools, poo) that are more frequent or more liquid. Diarrhoea 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. You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or Tiredness and lack of energy things you enjoy. (fatigue) • 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. • You may get muscle, joint or general body pain and stiffness. Joint and muscle pain and Applying a heat pack to affected areas may help. stiffness · Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain.

• This may be found from your routine blood tests and treated by your doctor. Low blood potassium levels • If it is severe you may get: (hypokalaemia) muscle cramps or twitches constipation confusion o an irregular heartbeat. • Tell your doctor or nurse as soon as possible if you get any of the signs or symptoms listed above. · You may get: Liver problems yellowing of your skin or eyes o itchy skin o pain or tenderness in your stomach nausea and vomiting loss of appetite You will have regular blood tests to check how well your liver is working. . 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. • If your nose starts to bleed gently apply pressure on the soft part of nostrils below the Nose bleeds bridge of the nose for at least 10 minutes. • It may help to put a cold pack over your forehead or the bridge of the nose. • Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if your nose will not stop bleeding. • The palms of your hands and soles of your feet may become: Hand-foot syndrome o red and hot (palmar-plantar swollen erythrodysaesthesia) painful and tender o blistered. • The skin in the area may also peel. • Moisturise your hands and feet daily with sorbolene or aqueous cream. • Keep your hands and feet clean and dry. • Avoid hot water, instead use lukewarm water to bathe. Avoid direct sunlight. Avoid unnecessary walking, jogging or exercise. · Wear cotton socks and avoid tight-fitting shoes. . Tell your doctor or nurse as soon as possible if you notice any skin changes on your hands or feet. • You may get a red, bumpy rash and dry, itchy skin. Skin rash · Moisturise your skin with a gentle non-perfumed moisturising cream like sorbolene or aqueous cream. · Do not scratch your skin. · Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and sunscreen of SPF 50 or higher. . Talk to your doctor or nurse about other ways to manage your skin rash.

Nerve damage (peripheral neuropathy)

- You may notice a change in the sensations in your hands and feet, including:
 - tingling or pins and needles
 - numbness or loss of feeling
 - pain
- You may find it difficult to do everyday activities, such as doing up buttons or picking up small objects.
- Test water temperature with your elbow when bathing to avoid burns.
- Use rubber gloves, pot holders and oven mitts in the kitchen.
- Wear rubber shoes or boots when working in the garden or garage.
- Keep rooms well lit and uncluttered.
- Ask your doctor or nurse for eviQ patient information Nerve problems during cancer treatment.
- Tell your doctor or nurse if you get any of the symptoms listed above.

Eye problems

- You may get:
 - eye pain
 - red, sore or swollen eyes
 - o blurred vision
 - watery or gritty eyes
 - changes in your eyesight
 - o sensitivity to sunlight.
- Protect your eyes from the weather (sun and wind) by wearing sunglasses, especially if you have lost your eyelashes.
- Tell your doctor or nurse if you get any of the symptoms listed above. Eye drops may help with your symptoms.

Late (onset weeks to months)

Low red blood cells (anaemia)

- You may feel dizzy, light-headed, tired and appear more pale than usual.
- Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion.
- Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.

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
 - o fast heartbeat
 - o 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.

Delayed (onset months to years)

Heart problems

- You may get:
 - chest pain or tightness
 - o shortness of breath
 - swelling of your ankles
 - o 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

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

Fertility

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

Pregnancy and breastfeeding

Some cancer treatments can be dangerous to unborn babies. Talk to your doctor or nurse if you think there is any chance that

you could be pregnant.

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

Sex life and sexuality

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

Quitting smoking

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

Staying active

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

For more information about cancer treatment, side effects and side effect management see our Patient and carers section.

Where to get more information

Telephone support

• Call Cancer Council on 13 11 20 for cancer information and support.

Breast cancer information

- Australasian Lymphology Association lymphoedema.org.au
- Australasian Menopause Society menopause.org.au
- Breast Cancer Network Australia bcna.org.au
- National Breast Cancer Foundation nbcf.org.au
- YWCA Encore breast cancer exercise program ywcaencore.org.au

General cancer information and support

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

Quit smoking information and support

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information

and support to help you quit smoking. Talk to your treating team about any other questions you may have.

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

| Additional notes: | | |
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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

First approved: 16 June 2014
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