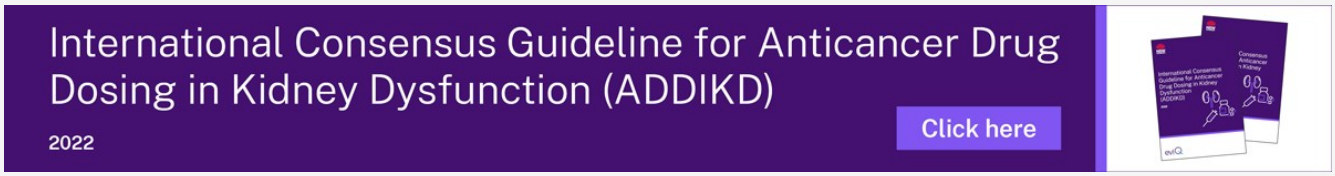
Breast adjuvant/neoadjuvant DOCEtaxel

ID: 4134 v.1 **Endorsed** Essential Medicine List

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

The anticancer drug(s) in this protocol may have been included in the ADDIKD guideline. Dose recommendations in kidney dysfunction have yet to be updated to align with the ADDIKD guideline. Recommendations will be updated once the individual protocol has been evaluated by the reference committee. For further information refer to the ADDIKD guideline. To assist with calculations, use the eviQ Estimated Glomerular Filtration Rate (eGFR) calculator.



Related pages:

- Breast neoadjuvant AC (DOXOrubicin and CYCLOPHOSPHamide) three weekly followed by DOCEtaxel three weekly overview
- Breast adjuvant EC-D (epirubicin and CYCLOPHOSPHamide followed by DOCEtaxel) overview
- Anti-cancer therapy before breast cancer surgery (neoadjuvant therapy)

Treatment schedule - Overview

Cycle 1 to 4

Drug	Dose	Route	Day
DOCEtaxel	100 mg/m^2	IV infusion	1
Pegfilgrastim	6 mg	Subcut	2

Frequency: 21 days

Cycles: 4

Notes:
For neoadjuvant treatment, docetaxel may given sequentially before or after an anthracycline-based regimen. It is the consensus of the eviQ reference committee that either order of administration is acceptable.

Drug status: Docetaxel is on the PBS general schedule

Pegfilgrastim is PBS authority

Cost: ~ $110 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 to 4

Day before chemotherapy		
Dexamethasone	8 mg (PO)	TWICE a day with or after food

Day 1		
Dexamethasone	8 mg (PO)	TWICE a day with or after food
DOCEtaxel	100 mg/m^2 (IV infusion)	in 250 mL to 500 mL sodium chloride 0.9% over 60 minutes

Day 2		
Dexamethasone	8 mg (PO)	TWICE a day with or after food
Pegfilgrastim	6 mg (Subcut)	inject subcutaneously on day 2 at least 24 hours after chemotherapy

Frequency: 21 days

Cycles: 4

Indications and patient population

- Adjuvant or neoadjuvant treatment of operable breast cancer.

Clinical information

Venous access required	IV cannula (IVC) or central venous access device (CVAD) is required to administer this treatment. Read more about central venous access device line selection
Hypersensitivity/infusion related reaction	High risk with docetaxel
Premedication	The product information states that premedication is required for this treatment. Please refer to the treatment schedule for the suggested premedication regimen. This may be substituted to reflect institutional policy. Read more about premedication for prophylaxis of taxane hypersensitivity reactions
Emetogenicity LOW	Dexamethasone has been included as both an antiemetic and premedication for hypersensitivity in this protocol. 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
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
Biosimilar drug	Read more about biosimilar drugs on the Biosimilar Awareness Initiative page

Growth factor support	G-CSF (short or long-acting) is available on the PBS for chemotherapy induced neutropenia depending on clinical indication and/or febrile neutropenia risk. Access the PBS website
Blood tests	FBC, EUC and LFTs at baseline and prior to each cycle.
Hepatitis B screening and prophylaxis	Routine screening for HBsAg and anti-HBc is recommended prior to initiation of treatment. Prophylaxis should be determined according to individual institutional policy. 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: all dose reductions are calculated as a percentage of the starting dose.

Haematological toxicity	
ANC x 10^9/L (pre-treatment blood test)	
0.5 to less than 1.0	Delay treatment until recovery
less than 0.5	Delay treatment until recovery and consider reducing docetaxel by 25% for subsequent cycles
Febrile neutropenia	Delay treatment until recovery and consider reducing docetaxel by 25% for subsequent cycles

Haematological toxicity	
Platelets x 10^9/L (pre-treatment blood test)	
75 to less than 100	Refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if patient is clinically well
50 to less than 75	Delay treatment until recovery
less than 50	Delay treatment until recovery and consider reducing docetaxel by 25% for subsequent cycles

Renal impairment
No dose modifications necessary

Hepatic impairment	
Hepatic dysfunction	
Minimal	Reduce docetaxel by 25%
Mild	Reduce docetaxel by 50%
Moderate/Severe	Omit docetaxel

Peripheral neuropathy	
Grade 2, which is present at the start of the next cycle	Reduce docetaxel by 25%; If persistent, reduce docetaxel by 50%
Grade 3 or Grade 4	Omit docetaxel

Mucositis and stomatitis	
Grade 2	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: 1st occurrence: No dose reduction 2nd occurrence: Reduce docetaxel by 25% 3rd occurrence: Reduce docetaxel by 50%
Grade 3 or Grade 4	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: 1st occurrence: Reduce docetaxel by 50% 2nd occurrence: Omit docetaxel

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*

Docetaxel		
	Interaction	**Clinical management**
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin, grapefruit juice etc.)	Increased toxicity of docetaxel possible due to reduced clearance	Avoid combination or monitor for docetaxel toxicity
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of docetaxel possible due to increased clearance	Avoid combination or monitor for decreased clinical response to docetaxel

General		
	Interaction	**Clinical management**
Warfarin	Anti-cancer drugs may alter the anticoagulant effect of warfarin.	Monitor INR regularly and adjust warfarin dosage as appropriate; consider alternative anticoagulant.
Direct oral anticoagulants (DOACs) e.g. apixaban, rivaroxaban, dabigatran	Interaction with both CYP3A4 and P-gp inhibitors /inducers. DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).	Apixaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. If treating VTE, avoid use with strong CYP3A4 and P-gp inducers. Rivaroxaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. Dabigatran: avoid combination with strong P-gp inducers and inhibitors. If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.
Digoxin	Anti-cancer drugs can damage the lining of the intestine; affecting the absorption of digoxin.	Monitor digoxin serum levels; adjust digoxin dosage as appropriate.
Antiepileptics	Both altered antiepileptic and anti-cancer drug levels may occur, possibly leading to loss of efficacy or toxicity.	Where concurrent use of an enzyme-inducing antiepileptic cannot be avoided, monitor antiepileptic serum levels for toxicity, as well as seizure frequency for efficacy; adjust dosage as appropriate. Also monitor closely for efficacy of the anti-cancer therapy.
Antiplatelet agents and NSAIDs	Increased risk of bleeding due to treatment related thrombocytopenia.	Avoid or minimise combination. If combination deemed essential, (e.g. low dose aspirin for ischaemic heart disease) monitor for signs of bleeding.
Serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs e.g. paroxetine) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. venlafaxine)	Increased risk of serotonin syndrome with concurrent use of 5-HT3 receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	Avoid combination. If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia). For more information link to TGA Medicines Safety Update
Vaccines	Diminished response to vaccines and increased risk of infection with live vaccines.	Live vaccines (e.g. BCG, MMR, zoster and varicella) are contraindicated in patients on immunosuppressive therapy. Use with caution in patients on non-immunosuppressive therapy. For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the Australian Immunisation Handbook

Administration

eviQ provides safe and effective instructions on how to administer cancer treatments. However, eviQ does not provide every treatment delivery option, and is unable to provide a comprehensive list of cancer treatment agents and their required IV line giving set/filter. There may be alternative methods of treatment administration, and alternative supportive treatments that are also appropriate. Please refer to the individual

product information monographs via the TGA website for further information.

Day 1

Approximate treatment time: 90 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.

Pre treatment medication

Verify taxane premedication taken or administer as prescribed.

Administer antiemetics if required

Chemotherapy - Time out

Docetaxel

Prior to administration:

- assess patient for fluid retention or weight gain prior to each cycle
  - notify medical officer of any signs of fluid retention or unexplained weight gain.

The medicines information reference publications stipulate the use of non-PVC containing bags and administration sets. However, this is not consistently recommended in the product information, therefore the decision should be at the discretion of the administering unit.

Administer docetaxel (irritant with vesicant properties):

- via IV infusion over 60 minutes
- observe for hypersensitivity reactions
- flush with ~ 100 mL of sodium chloride 0.9%.

Stop infusion at first sign of reaction:

- if symptoms are mild and resolve when infusion is stopped, consider recommencing infusion after review by medical officer at a slower rate.
- for severe reactions seek medical assistance immediately and do not restart infusion.

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.

Dexamethasone tablets

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

Growth factor support

- Arrangements for administration if prescribed.

Patient information

- Ensure patient receives patient information sheet.

Side effects

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

Immediate (onset hours to days)	
Hypersensitivity reaction	Anaphylaxis and infusion related reactions can occur with taxanes. Read more about premedication for prophylaxis of taxane hypersensitivity reactions
Nausea and vomiting	Read more about prevention of treatment induced nausea and vomiting
Taste and smell alteration	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. Read more about thrombocytopenia
Fatigue	Read more about fatigue
Oral mucositis	Erythematous and ulcerative lesions of the gastrointestinal tract (GIT). It commonly develops following chemotherapy, radiation therapy to the head, neck or oesophagus, and high dose chemotherapy followed by a blood and marrow transplant (BMT). Read more about oral mucositis
Diarrhoea	Read more about treatment induced diarrhoea
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
Ocular changes	Symptoms may include eye pain, blurred vision, blepharitis, uveitis, optic neuritis, tear duct stenosis, conjunctivitis, hyperlacrimation, watery or dry eyes and photophobia.
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
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
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
Fluid retention syndrome	Fluid retention, including peripheral oedema and weight gain, may occur with docetaxel treatment. The main risk factor for development is cumulative docetaxel dose. Pre-medication with dexamethasone may be used. Fluid retention will slowly resolve after cessation of treatment. Read more about fluid retention syndrome associated with docetaxel

Late (onset weeks to months)	
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood. Read more about anaemia
Nail changes	Hyperpigmentation, paronychia, onycholysis, splinter haemorrhage, pyogenic granuloma formation, subungal haematoma and subungal hyperkeratosis are some of the nail changes associated with anti-cancer drugs. Read more about nail toxicities
Alopecia - partial	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 alopecia

Delayed (onset months to years)	
Menopausal symptoms	Irregular or absent periods, hot flushes, mood swings, sleep disturbance, night sweats, vaginal dryness, decreased libido and dyspareunia. This is caused by ovarian failure and may be temporary or permanent.

Evidence - Adjuvant EC-D

The evidence supporting this protocol is provided by a phase III multicentre international randomised trial ADEBAR involving 1364 patients comparing FEC120 with EC-D in patients with node positive breast cancer.[1] FEC120 has previously been shown to be superior to three-weekly AC-paclitaxel and equivalent to EC-paclitaxel in the MA21 trial.[2]

Between September 2001 and May 2005, a total of 748 patients were randomised to four 21-day cycles of EC-D (epirubicin 90 mg/m^2 and cyclophosphamide 600 mg/m^2 on day 1) followed by four 21-day cycles of docetaxel 100 mg/m^2 on day 1, and 745 patients were randomised to six 28-day cycles of FEC120 (epirubicin 60 mg/m^2 and 5-fluorouracil 500 mg/m^2 IV on day 1 and 8, plus cyclophosphamide 75 mg/m^2 PO on day 1-14). Hormone-receptor positive breast cancer patients received appropriate endocrine therapy at the end of chemotherapy for 5 years.

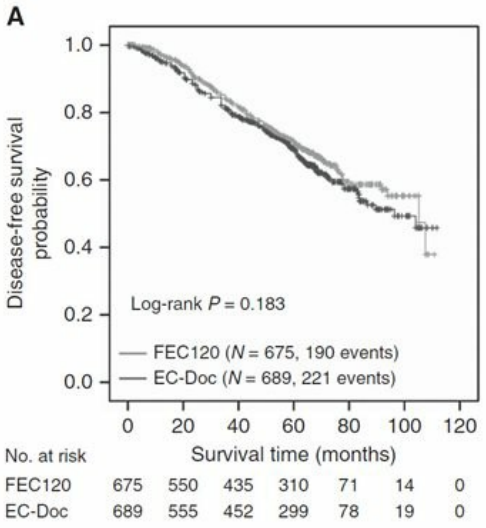
The primary end point was 5-year disease-free survival (DFS) and secondary end points were overall survival (OS) and toxicity.

Efficacy

After a median follow up of 5 years, the DFS was 74% in the EC-D group and 76.9% in the FEC120 group with no difference in treatment confirmed on multivariate cox regressions adjusting for other prognostic variables (HR 1.087, 95% CI, 0.878 to 1.346, p=0.444).

5-year OS rates were 80.6% in both the EC-D and FEC120 groups (p=0.841).[1]

Kaplan-Meier curve for disease-free survival[1]



Toxicity

The rate of serious adverse events was significantly higher in the FEC120 treatment arm than those patients treated with EC-D (29.7% versus 22.5%, p=0.003) and significantly more patients ceased treatment prematurely in the FEC120 arm than with EC-D (8.3% versus 4.2%, p=0.002).[1]

Similarly more patients in the FEC120 arm required dose reductions (6.2% versus 2.7%, p<0.001), delays to chemotherapy delivery (8.5% versus 5.9%, p<0.001) and supportive treatments such as G-CSF, EPO stimulation or antibiotic therapy (p<0.001).

Adverse events[1]

Toxicity (≥ grade 3)	EC-D n = 684	FEC120 n = 674

Toxicity (≥ grade 3)	EC-D n = 684	FEC120 n = 674
Neutropenia (%)	59.4	62.3
Anaemia (%)	2.8	15.6
Thrombocytopenia (%)	1.9	23.7
Infection (%)	9.6	15.4
Nausea (%)	1.2	1.6
Vomiting (%)	3.5	1.8
Diarrhoea (%)	1.0	1.8
Mucositis (%)	7.6	8.8
Arthralgia/myalgia (%)	8.3	1.2
Cardiac toxicity (%)	0.1	0.6
Neurological symptoms (%)	0.7	0.1

Evidence - Neoadjuvant AC three weekly followed by docetaxel three weekly

The evidence supporting this protocol is provided by the NSABP B-27 trial, which was a phase III multicentre trial designed to determine the effect of adding docetaxel (T) to preoperative doxorubicin and cyclophosphamide (AC) on breast cancer response rates and disease-free survival (DFS) and overall survival (OS).[3]

Between December 1995 and December 2000, 2411 patients were randomly assigned to receive preoperative AC followed by surgery (n=784), AC followed by T and surgery (n=783), or AC followed by surgery then T (n=777) in patients with operable breast cancer.[3]

AC: Doxorubicin 60 mg/m^2 and cyclophosphamide 600 mg/m^2 every 21 days for 4 cycles

T: Docetaxel 100 mg/m^2 every 21 days for 4 cycles

All patients received tamoxifen 20 mg/day for 5 years on the first day of chemotherapy regardless of hormone receptor status and this may have limited the impact of adding docetaxel.

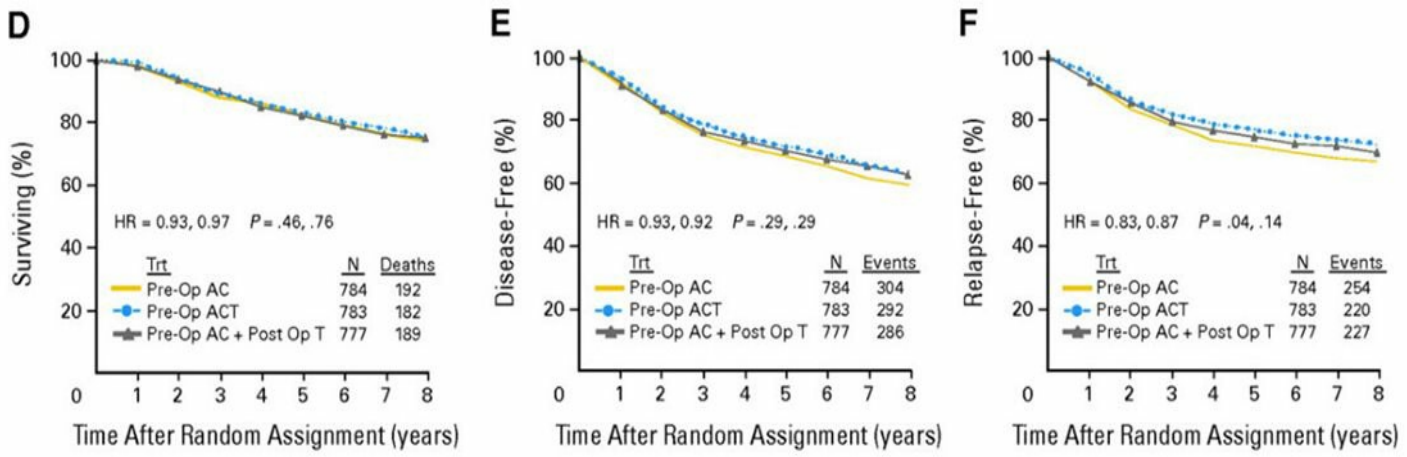
The primary end points were OS, DFS, and relapse-free interval (RFI).[3]

Efficacy

After a median follow up of 8.5 years, 86% of the patients in the two groups assigned to receive preoperative AC only (groups 1 and 3) achieved a clinical response compared with 91% of patients in the preoperative AC and T group (P<0.001). The cCR rate was increased from 40% to 63% with the addition of four cycles of docetaxel (P<0.001). The pCR rate was increased from 13% in groups 1 and 3 to 26% in group 2 (P<0.001).[4]

Although there were trends toward improved DFS with addition of T, this was not significant nor was there a significant effect on OS.

(D) Overall survival (OS), (E) Disease-free survival (DFS), (F) Relapse-free interval, in NSABP B-27 trial [4]



Toxicity

81% of patients completed docetaxel therapy to the planned schedule. The improved responses achieved with docetaxel were at the expense of some increased toxicity. Grade 4 toxicity was observed in 10% of patients during treatment with AC and 23% of patients during administration of docetaxel. Febrile neutropenia occurred in 21% of patients receiving docetaxel versus 7% of those receiving AC alone. However, no significant increase in neutropenic infection was observed with docetaxel usage. Non-haematological toxicities were generally mild in both groups (<1% grade 4).[5]

The following toxicity table is adapted from the phase II GeparDUO trial.[6]

Toxicity (n=176) [6]	Grade 3/4 (%)
Anaemia	4.5*
Neutropenia	69.3**
Thrombocytopenia	2.8
Alopecia	93.8
Fluid retention	0
Infection	1.1
Nausea/vomiting	15.3***
Sensory and/or motor neuropathy	7.4
Fatigue	26.7
Skin and/or nail disorders	10.8

*Percentages are based on the number of evaluable patients which varied as noted: *n=178, **n=166, ***n=177*

References

1 Janni, W., N. Harbeck, B. Rack, et al. 2016. "Randomised phase III trial of FEC120 vs EC-docetaxel in patients with high-risk node-positive primary breast cancer: final survival analysis of the ADEBAR study." Br J Cancer 114:863.

2 Burnell, M., M. N. Levine, J. A. Chapman, et al. 2010. "Cyclophosphamide, epirubicin, and Fluorouracil versus dose-dense epirubicin and cyclophosphamide followed by Paclitaxel versus Doxorubicin and cyclophosphamide followed by Paclitaxel in node-positive or high-risk node-negative breast cancer." J Clin Oncol 28(1):77-82.

3 Bear, H. D., S. Anderson, R. E. Smith, et al. 2006. "Sequential preoperative or postoperative docetaxel added to preoperative doxorubicin plus cyclophosphamide for operable breast cancer:National Surgical Adjuvant Breast and Bowel Project Protocol B-27." J Clin Oncol 24(13):2019-2027.

4 Rastogi, P., S. J. Anderson, H. D. Bear, et al. 2008. "Preoperative chemotherapy: updates of National Surgical Adjuvant Breast and Bowel Project Protocols B-18 and B-27." J Clin Oncol 26(5):778-785.

5 Heys, S. D., T. Sarkar and A. W. Hutcheon. 2005. "Primary docetaxel chemotherapy in patients with breast cancer: impact on response and survival." Breast Cancer Res Treat 90(2):169-185.

6 Jackisch, C., G. von Minckwitz, H. Eidtmann, et al. 2002. "Dose-dense biweekly doxorubicin/docetaxel versus sequential neoadjuvant chemotherapy with doxorubicin/cyclophosphamide/docetaxel in operable breast cancer: second interim analysis." Clin Breast Cancer 3(4):276-280.

History

Version 1

Date	Summary of changes
05/08/2022	New protocol approved at Medical Oncology Reference Committee meeting.
30/08/2022	Protocol published on eviQ. Next review in 2 years.

As ID 4134 Breast adjuvant/neoadjuvant DOCEtaxel replaces two existing approved protocols, their individual History sections are included below for consistency in documentation.

ID 3915 Breast adjuvant D (DOCEtaxel) (part 2 of EC-D) version 1	
Date	**Summary of changes**
13/08/2021	New protocol approved by Medical Oncology Reference Committee.
09/09/2021	Protocol published on eviQ. Review in 1 year.

ID 1325 Breast neoadjuvant DOCEtaxel three weekly (part 2) version 4	
Date	**Summary of changes**
27/04/2012	New protocol taken to Medical Oncology Reference Committee meeting.
15/06/2012	Approved and published on eviQ.
30/06/2013	Protocol reviewed by committee via email survey. No changes and next review in 2 years.
25/07/2014	Amendment: G-CSF is not PBS reimbursed.
22/06/2015	Protocol reviewed electronically by Medical Oncology Reference committee. No changes and next review in 2 years.
31/05/2017	Transferred to new eviQ website. Protocol version number changed to V.2.
03/11/2017	Reviewed by Medical Oncology Reference Committee. No changes. Review in 5 years.
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.3.
08/10/2019	Clinical information updated with PBS expanded indications for GCSF.

First approved: 5 August 2022
Review due: 31 December 2024

The currency of this information is guaranteed only up until the date of printing, for any updates please check:
https://www.eviq.org.au/p/4134
08 Jun 2023

Patient information - Breast cancer adjuvant/neoadjuvant - Docetaxel

Patient's name:

Your treatment

This treatment can be given either before or after surgery. The aim of neoadjuvant (before surgery) treatment is to shrink the tumour to make it easier to remove. Your doctor will advise which treatment plan is recommended for you.

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

Docetaxel			
This treatment cycle is repeated every 21 days. You will have 4 cycles. Your doctor will discuss your treatment plan with you.			
Day	**Treatment**	**How it is given**	**How long it takes**
1	**Docetaxel** (*dox-e-tax-elle*)	By a drip into a vein	About 1.5 hours
2	**Pegfilgrastim** *(peg-fil-GRA-stim)*	By injection under the skin	About 5 minutes

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.

Treatment before surgery (neoadjuvant therapy)

For more information see the eviQ patient information sheet on Anti-cancer therapy before breast cancer surgery (neoadjuvant therapy).

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.
- **G-CSF:** you will be given injection(s) of a drug called G-CSF (also called filgrastim, lipegfilgrastim or pegfilgrastim) under your skin. This helps to boost your white blood cell count. Your white blood cells help to fight infection. Lipegfilgrastim and pegfilgrastim are given once. Filgrastim is given for several days until your white blood cells recover.
- **Docetaxel premedication:** before your treatment with docetaxel you may need to take a tablet called a premedication to help prevent you from having a reaction to docetaxel. A steroid tablet called dexamethasone may be used and should be taken with or after food as directed. The following table may be used to remind you when to take your premedication. Ask your doctor, nurse or pharmacist to fill it out for you.

Tablet	Dose	When to take

Tell your doctor or nurse if you have not taken your premedications before you have your treatment.

Side effects

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

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

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

Immediate (onset hours to days)	

Allergic reaction	• Allergic reactions are uncommon but can be life threatening.
	• **If you feel unwell during the infusion or shortly after it, or:**
	  ◦ **get a fever, shivers or shakes**
	  ◦ **feel dizzy, faint , confused or anxious**
	  ◦ **start wheezing or have difficulty breathing**
	  ◦ **have a rash, itch or redness of the face**
	
	<u>While you are in hospital:</u> Tell your doctor or nurse immediately.
	<u>After you leave:</u> Contact your doctor or nurse immediately, or go to the nearest hospital Emergency Department.

Nausea and vomiting	• You may feel sick (nausea) or be sick (vomit). • Take your anti-sickness medication as directed even if you don't feel sick. • Drink plenty of fluids (unless you are fluid restricted). • Eat small meals more frequently. • Try food that does not require much preparation. • Try bland foods like dry biscuits or toast. • Gentle exercise may help with nausea. • Ask your doctor or nurse for eviQ patient information - Nausea and vomiting during cancer treatment. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have uncontrolled vomiting or feel dizzy or light-headed.**
Taste and smell changes	• You may find that food loses its taste or tastes different. • These changes are likely to go away with time. • Do your mouth care regularly. • Chew on sugar-free gum or eat sugar-free mints. • Add flavour to your food with sauces and herbs. • Ask your doctor or nurse for eviQ patient information - Taste and smell changes during cancer treatment.

Early (onset days to weeks)	

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

Low platelets (thrombocytopenia)	• This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising. • Try not to bruise or cut yourself. • Avoid contact sport or vigorous exercise. • Clear your nose by blowing gently. • Avoid constipation. • Brush your teeth with a soft toothbrush. • Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to. • Tell your doctor or nurse if you have any bruising or bleeding. • **Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.**
Tiredness and lack of energy (fatigue)	• You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or things you enjoy. • Do not drive or operate machinery if you are feeling tired. • Nap for short periods (only 1 hour at a time) • Prioritise your tasks to ensure the best use of your energy. • Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted). • Try some gentle exercise daily. • Allow your friends and family to help. • **Tell your doctor or nurse if you get any of the symptoms listed above.**
Mouth pain and soreness (mucositis)	• You may have: ◦ bleeding gums ◦ mouth ulcers ◦ a white coating on your tongue ◦ pain in the mouth or throat ◦ difficulty eating or swallowing. • Avoid spicy, acidic or crunchy foods and very hot or cold food and drinks. • Try bland and soft foods. • Brush your teeth gently with a soft toothbrush after each meal and at bedtime. If you normally floss continue to do so. • Rinse your mouth after you eat and brush your teeth, using either: ◦ 1/4 teaspoon of salt in 1 cup of warm water, or ◦ 1/4 teaspoon of bicarbonate of soda in 1 cup of warm water • Ask your doctor or nurse for eviQ patient information - Mouth problems during cancer treatment. • **Tell your doctor or nurse if you get any of the symptoms listed above.**
Diarrhoea	• You may get bowel motions (stools, poo) that are more frequent or more liquid. • You may also get bloating, cramping or pain. • Take your antidiarrhoeal medication as directed by your doctor. • Drink plenty of fluids (unless you are fluid restricted). • Eat and drink small amounts more often. • Avoid spicy foods, dairy products, high fibre foods, and coffee. • Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. • **Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed.**
Skin rash	• You may get a red, bumpy rash and dry, itchy skin. • Moisturise your skin with a gentle non-perfumed moisturising cream like sorbolene or aqueous cream. • Do not scratch your skin. • Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and sunscreen of SPF 50 or higher. • **Talk to your doctor or nurse about other ways to manage your skin rash.**

Eye problems	• You may get:
	  ◦ eye pain
	  ◦ red, sore or swollen eyes
	  ◦ blurred vision
	  ◦ watery or gritty eyes
	  ◦ changes in your eyesight
	  ◦ 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.**

Joint and muscle pain and stiffness	• You may get muscle, joint or general body pain and stiffness. • Applying a heat pack to affected areas may help. • Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain.

Hand-foot syndrome (palmar-plantar erythrodysaesthesia)	• The palms of your hands and soles of your feet may become:
	  ◦ red and hot
	  ◦ swollen
	  ◦ painful and tender
	  ◦ 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.**

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.

Extra fluid in the body (fluid retention)	• You may gain weight over a short amount of time. • Your hands and feet may become swollen, appear red or feel hot and uncomfortable. • These symptoms are caused by the drug docetaxel. • Wear loose clothing and shoes that are not too tight. • Try not to stand up or walk around too much at one time. • If your ankles or legs get swollen, try raising them. • Make sure that any cuts or areas of broken skin are treated as soon as possible. • **Tell your doctor or nurse as soon as possible if you get any of the symptoms listed above.** • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you become short of breath.**

Late (onset weeks to months)	
Low red blood cells (anaemia)	• You may feel dizzy, light-headed, tired and appear more pale than usual. • Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.**
Nail changes	• Your nails may: ◦ grow more slowly ◦ become darker ◦ develop ridges or white lines ◦ become brittle and flaky • In some cases, you may lose your nails completely. • Keep your nails clean and short. • Avoid things like biting your fingernails, getting a manicure, pedicure or false nails. • Wear gloves when you wash the dishes, work in the garden, or clean the house.
Hair thinning	• Your hair may become dry and may break easily. • You may lose some of your hair. • Use a gentle shampoo and a soft hairbrush. • Take care with hair products like hairspray, hair dye, bleaches and perms. • Protect your scalp from the cold with a hat or scarf. • Protect your scalp from the sun with a hat and sunscreen of SPF 50 or higher. • Ask your doctor or nurse about the Look Good Feel Better program (www.lgfb.org.au)

Delayed (onset months to years)	
Menopausal symptoms	• You may get: ◦ hot flushes or night sweats ◦ mood changes ◦ vaginal dryness ◦ irregular or no periods. • You may also: ◦ have trouble sleeping ◦ find sex painful or lose interest in sex • These symptoms may go away after treatment, or the menopause may be permanent. • If you have sex you should use contraception as there is still a risk of pregnancy. Talk to your doctor about what form of contraception is right for you. • Talk to your doctor or nurse about ways to manage these symptoms.

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 – lgfb.org.au
- Patient Information – patients.cancer.nsw.gov.au
- Radiation Oncology Targeting Cancer – targetingcancer.com.au
- Redkite – redkite.org.au
- Return Unwanted Medicines – returnmed.com.au
- Staying active during cancer treatment – patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active

Quit smoking information and support

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information and support to help you quit smoking. Talk to your treating team about any other questions you may have.

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

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The currency of this information is guaranteed only up until the date of printing, for any updates please check:
https://www.eviq.org.au/pi/4134
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