

Breast adjuvant abemaciclib

ID: 4168 v.1 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)

2022

Click here



Related pages:

- · Breast adjuvant anastrozole
- · Breast adjuvant exemestane
- · Breast adjuvant goserelin
- · Breast adjuvant letrozole
- · Breast adjuvant tamoxifen

Treatment schedule - Overview

Drug	Dose	Route
Abemaciclib	150 mg TWICE a day	PO

Continuous daily for 2 years or until disease recurrence or unacceptable toxicity

Notes

- Abemaciclib is given in combination with hormonal therapy. See Indications and patient population section below.
- In the trial, treatment was initiated at least 21 days post last adjuvant chemotherapy/at least 14 days post adjuvant radiation therapy if indicated.¹

Drug status: Abemaciclib is TGA registered but not PBS listed for this indication.

Abemaciclib is available as $50 \, mg$, $100 \, mg$, and $150 \, mg$ tablets

Cost: ~ \$4,280 per month

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.

Continuous treatment

Breast adjuvant abemaciclib Page 1 of 10

Abemaciclib 150 mg (PO) TWICE a day

- Abemaciclib is given in combination with hormonal therapy. See Indications and patient population section below.
- In the trial, treatment was initiated at least 21 days post last adjuvant chemotherapy/at least 14 days post adjuvant radiation therapy if indicated.¹

Continuous daily for 2 years or until disease recurrence or unacceptable toxicity

Indications and patient population

Indications:

- High-risk, node-positive, hormone receptor (HR) positive, HER-2 negative, invasive early breast cancer in combination with an aromatase inhibitor following definitive surgery, with or without radiation therapy/chemotherapy
 - High-risk feature is defined based on presence of ≥4 positive pathologic axillary lymph nodes or 1-3 positive axillary lymph nodes with at least one of the following: tumour size >5cm, histological grade 3, or centrally assessed Ki-67 ≥20%.
 - In pre- or peri-menopausal women, the aromatase inhibitor should be combined with a GnRH agonist (e.g. goserelin), starting 4 weeks prior to commencing abemaciclib.
 - ECOG performance status 0 to 1.

Note:

Fulvestrant was not permitted in the study.¹

Clinical information

Caution with oral anti-cancer drugs	Select links for information on the safe prescribing, dispensing and administration of orally administered anti-cancer drugs.
	Read more about the COSA guidelines and oral anti-cancer therapy
Emetogenicity minimal or low	No routine prophylaxis required. If patients experience nausea and/or vomiting, consider using the low emetogenic risk regimen.
	Read more about preventing anti-cancer therapy induced nausea and vomiting
Pneumonitis	Pneumonitis, including some fatal cases, has been reported in a small number of patients receiving this treatment. Monitor patient for new or worsening respiratory symptoms such as dyspnoea, cough and fever, or a radiological abnormality. If pneumonitis is suspected, this treatment should be withheld and prompt investigation initiated. If pneumonitis is confirmed, this treatment should be discontinued.
Thromboembolism	Venous thromboembolic events have been observed in patients with this treatment.
Surgery	Caution is advised for any surgical procedures required during CDK4/6 inhibitor treatment. Consider interrupting CDK4/6 inhibitor treatment for at least 7 days prior to major surgeries and reinitiating postoperatively once satisfactory wound healing has occurred.
Diarrhoea	Antidiarrhoeals (e.g. loperamide) are usually prescribed with this treatment. Read more about treatment induced diarrhoea
Growth factor support	G-CSF may be required. Refer to dose modifications section of the protocol.
Blood tests	FBC, EUC, LFTs at baseline. Repeat FBC and LFTs every 2 weeks for the first 2 months, monthly for the next 2 months then as clinically indicated. Repeat EUC as clinically indicated.
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

Breast adjuvant abemaciclib Page 2 of 10

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:

 The following dose modification recommendations have been adapted from the clinical trial and the abemaciclib product information.¹

Abemaciclib dose modifications for adverse events

Dose level	Dose
Recommended dose	150 mg twice a day
First dose reduction	100 mg twice a day
Second dose reduction	50 mg twice a day

Note: If further dose reduction below 50 mg twice a day is required, discontinue abemaciclib.

Haematological toxicity	
ANC x 10 ⁹ /L	
0.5 to less than 1.0	Withhold abemaciclib until ANC ≥ 1.0, then resume abemaciclib as follows:
	1st occurrence: no dose modification necessary
	Subsequent occurrences: next lower dose level

Breast adjuvant abemaciclib Page 3 of 10

Haematological toxicity	
less than 0.5	Withhold abemaciclib until ANC ≥ 1.0, then resume abemaciclib at the next lower dose level
Febrile neutropenia	Withhold abemaciclib until ANC \geq 1.0 and fever resolved, then resume abemaciclib at the next lower dose level If G-CSF is required, withhold abemaciclib for at least 48 hours after the last G-CSF administration and until ANC \geq 1.0, then resume abemaciclib at the next lower dose level (unless already reduced due to the toxicity that resulted in use of G-CSF)
Platelets x 10 ⁹ /L	
25 to less than 50	Withhold abemaciclib until platelets ≥ 50, then resume abemaciclib as follows: 1st occurrence: no dose modification necessary Subsequent occurrences: next lower dose level
less than 25	Withhold abemaciclib until platelets ≥ 50, then resume abemaciclib at the next lower dose level

Renal impairment	
Mild to moderate (CrCl ≥ 30 mL/min)	No dose modification necessary
Severe (CrCl < 30 mL/min)	Abemaciclib has not been studied in patients with severe renal impairment

Hepatic impairment	
Hepatic dysfunction (at baseline)	
Mild or moderate	No dose modification necessary
Severe	Start at 150 mg once a day
Hepatotoxicity (during treatment)	
ALT grade 2 (> 3 to 5 x ULN)	1st occurrence: no dose interruption necessary Subsequent occurrences: withhold abemaciclib until toxicity has resolved to baseline grade or grade 1, then resume abemaciclib at the next lower dose level
ALT grade 3 (> 5 to 20 x ULN)	Withhold abemaciclib until toxicity has resolved to baseline grade or grade 1, then resume abemaciclib at the next lower dose level
ALT grade 4 (> 20 x ULN)	Cease abemaciclib

<u>Diarrhoea</u>	
Grade 1	Start treatment with antidiarrhoeal agents e.g. loperamide. No dose modification necessary
Grade 2	Start treatment with antidiarrhoeal agents e.g. loperamide. If diarrhoea does not resolve within 24 hours to ≤ grade 1, withhold abemaciclib until diarrhoea ≤ grade 1, then resume abemaciclib as follows: 1st occurrence: no dose modification necessary Persistent or subsequent occurrences: next lower dose level
Grade 3 or 4	Start treatment with antidiarrhoeal agents e.g. loperamide. Withhold abemaciclib until diarrhoea ≤ grade 1, then resume abemaciclib at the next lower dose level

Interstitial lung disease (ILD)/ pneumonitis	
Persistent or recurrent Grade 2 that does not resolve with maximal	Withhold abemaciclib until toxicity has resolved to baseline or grade 1, then resume abemaciclib at the next lower dose level

Breast adjuvant abemaciclib Page 4 of 10

supportive measures to baseline or Grade 1 within 7 days	
Grade 3 or 4	Cease abemaciclib

Other toxicities	
Persistent or recurrent Grade 2 that does not resolve with maximal supportive measures to baseline or Grade 1 within 7 days OR Grade 3 or 4	Withhold abemaciclib until toxicity has resolved to ≤ grade 1 then resume abemaciclib at the next lower dose level

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

Abemaciclib				
	Interaction	Clinical management		
CYP3A4 inhibitors (e.g. amiodarone, aprepitant, azole antifungals, ritonavir, macrolides, grapefruit juice etc.)	Increased toxicity of abemaciclib possible due to reduced clearance	Avoid combination or monitor for abemaciclib toxicity. If concomitant use of ketoconazole cannot be avoided, reduce abemaciclib starting dose to 50 mg once a day (based on 150 mg twice a day starting dose). If concomitant use of clarithromycin, diltiazem or verapamil cannot be avoided, reduce abemaciclib starting dose to 100 mg twice a day. If concomitant use of other strong CYP3A4 inhibitors cannot be avoided, reduce abemaciclib starting dose to 50 mg twice a day. If concomitant use of moderate CYP3A4 inhibitor cannot be avoided, monitor for toxicity and consider reducing abemaciclib dose in 50 mg decrements. If CYP3A4 inhibitor is ceased, increase abemaciclib to previous dose (after 3 to 5 half-lives of the CYP3A4 inhibitor).		
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of abemaciclib possible due to increased clearance	Avoid combination or monitor for decreased effect of abemaciclib		

Administration

Breast adjuvant abemaciclib Page 5 of 10

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.

Administration

This is a continuous oral treatment

Safe handling and waste management (reproductive risk only)

Safe administration

General patient assessment prior to each treatment.

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

② Treatment - Time out

Abemaciclib

- administer orally TWICE a day (preferably at the same time each day, 12 hours apart)
- · to be swallowed whole with a glass of water; do not break, crush or chew

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

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

Discharge information

Abemaciclib tablets

· Abemaciclib tablets with written instructions on how to take them.

Antidiarrhoeals

· Antidiarrhoeals 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)

Nausea and vomiting Read more about prevention of treatment induced nausea and vomiting

Breast adjuvant abemaciclib Page 6 of 10

Early (onset days to weeks)	
Neutropenia	Abnormally low levels of neutrophils in the blood. This increases the risk of infection. Any fever or suspicion of infection should be investigated immediately and managed aggressively. Read more about immediate management of neutropenic fever
Thrombocytopenia	A reduction in the normal levels of functional platelets, increasing the risk of abnormal bleeding. Read more about thrombocytopenia
Diarrhoea	Read more about treatment induced diarrhoea
Fatigue	Read more about fatigue
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.
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

Late (onset weeks to months)				
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			
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood. Read more about anaemia			
Thromboembolism	Arterial and venous thromboembolic events, including pulmonary embolism, deep vein thrombosis and cerebrovascular accidents can occur. Patients should be carefully assessed for risk factors, and consideration given for antithrombotic prophylaxis in high risk patients.			

Evidence

The evidence supporting this protocol is provided by an open-label, multi-centre, phase III trial (monarchE) that investigated standard adjuvant endocrine therapy (ET) with/without abemaciclib after completion of surgery, radiation therapy and chemotherapy in patients with high-risk hormone receptor positive, HER-2 negative invasive early breast cancer. High-risk feature was defined based on presence of \geq 4 positive pathologic axillary lymph nodes or 1-3 positive axillary lymph nodes with at least one of the following: tumour size >5cm, histological grade 3, or centrally assessed Ki-67 \geq 20%.

Between July 2017 and August 2019, 5637 patients were randomised 1:1 to receive ET either with abemaciclib (150 mg PO twice daily for 2 years) (n=2808) or with placebo (n=2829).

The primary endpoint was invasive disease free survival (IDFS), and secondary end points included distant relapse-free survival (DRFS), overall survival (OS) and safety.

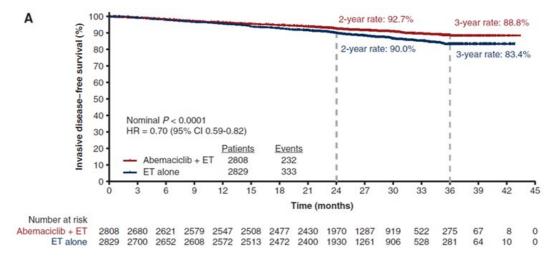
Efficacy

After a median follow up of 27 months, there were 232 (8.2%) IDFS events in the abemaciclib plus ET group and 333 (11.8%) in the ET alone group (HR=0.70; 95% CI, 0.59-0.82; p < 0.0001). 3-year DRFS rates were 90.3% in the abemaciclib plus ET arm and 86.1% in the control arm (HR=0.69; 95% CI, 0.57-0.83; p < 0.0001). 2

OS data remained immature, however at the first interim analysis there were 39 (1.4%) deaths observed in the abemaciclib arm and 37 (1.3%) observed in the control arm.¹

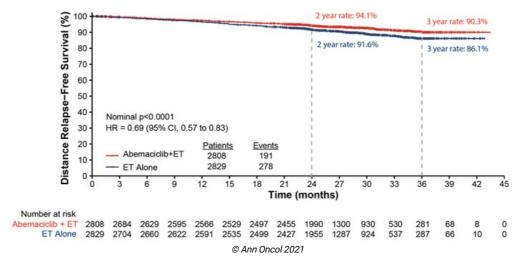
Kaplan-Meier curve of IDFS in the intent-to-treat (ITT) population²

Breast adjuvant abemaciclib Page 7 of 10



© Ann Oncol 2021

Kaplan-Meier curve of DRFS in the intent-to-treat (ITT) population²



Toxicity

A summary of the toxicities associated with this protocol are included in the table below. Overall, a higher incidence of grade ≥3 and serious toxicities were observed with abemaciclib plus ET vs ET alone (50% vs 16%; and 15% vs 9%, respectively). The most clinically significant toxicities (>30%) for this treatment were diarrhoea, neutropaenia, fatigue, leukopaenia and abdominal pain. Treatment discontinuation due to toxic events occurred in 6.5% of patients in the treatment arm vs 1.1% in the control arm.² At the time of interim analysis, there were 11 treatment-related deaths in the treatment arm as compared with 7 in the control arm.¹

Adverse events²

Breast adjuvant abemaciclib Page 8 of 10

≥10% in either arm	Abemaciclib+ ETN=2791, n (%)		ET alone N=2800, n (%)			
	Any grade	Grade 3	Grade 4	Any grade	Grade 3	Grade 4
Any adverse event	2745 (98.4%)	1284 (46.0%)	89 (3.2%)	2486 (88.8%)	424 (15.1%)	22 (0.8%)
Diarrhea	2331 (83.5%)	218 (7.8%)	0ª	242 (8.6%)	6 (0.2%)	0
Neutropenia	1278 (45.8%)	527 (18.9%)	19 (0.7%)	157 (5.6%)	19 (0.7%)	4 (0.1%)
Fatigue	1133 (40.6%)	80 (2.9%)	NAb	499 (17.8%)	4 (0.1%)	NAb
Leukopenia	1049 (37.6%)	313 (11.2%)	4 (0.1%)	186 (6.6%)	11 (0.4%)	NA ^b
Abdominal pain	992 (35.5%)	39 (1.4%)	NAb	275 (9.8%)	9 (0.3%)	NA ^b
Nausea	824 (29.5%)	14 (0.5%)	NAb	252 (9.0%)	2 (0.1%)	NAb
Arthralgia	742 (26.6%)	9 (0.3%)	NA ^b	1060 (37.9%)	29 (1.0%)	NA ^b
Anemia	681 (24.4%)	56 (2.0%)	1 (0.0%)	104 (3.7%)	9 (0.3%)	1 (0.0%)
Headache	546 (19.6%)	8 (0.3%)	NA ^b	421 (15.0%)	5 (0.2%)	NA ^b
Vomiting	491 (17.6%)	15 (0.5%)	0	130 (4.6%)	3 (0.1%)	0
Hot flush	427 (15.3%)	4 (0.1%)	NAb	643 (23.0%)	10 (0.4%)	NA ^b
Lymphopenia	395 (14.2%)	148 (5.3%)	3 (0.1%)	96 (3.4%)	13 (0.5%)	0
Cough	391 (14.0%)	1 (0.0%)	NA ^b	222 (7.9%)	0	NA ^b
Thrombocytopenia	373 (13.4%)	28 (1.0%)	8 (0.3%)	52 (1.9%)	2 (0.1%)	2 (0.1%)
Lymphedema	347 (12.4%)	5 (0.2%)	NA ⁶	250 (8.9%)	1 (0.0%)	NA ^b
Alanine aminotransferase increase	343 (12.3%)	72 (2.6%)	5 (0.2%)	157 (5.6%)	19 (0.7%)	0
Urinary tract infection	336 (12.0%)	16 (0.6%)	0	211 (7.5%)	6 (0.2%)	0
Constipation	333 (11.9%)	2 (0.1%)	0	168 (6.0%)	1 (0.0%)	0
Aspartate aminotransferase increased	330 (11.8%)	49 (1.8%)	3 (0.1%)	137 (4.9%)	15 (0.5%)	0
Decreased appetite	329 (11.8%)	16 (0.6%)	0	68 (2.4%)	2 (0.1%)	0
Alopecia	313 (11.2%)	NA°	NA¢	75 (2.7%)	NA¢	NAc
Rash	312 (11.2%)	11 (0.4%)	0	127 (4.5%)	0	0
Blood creatinine increased	311 (11.1%)	3 (0.1%)	0	23 (0.8%)	0	0
Dizziness	304 (10.9%)	4 (0.1%)	NAb	188 (6.7%)	1 (0.0%)	NA ^b
Upper respiratory tract infection	301 (10.8%)	6 (0.2%)	0	238 (8.5%)	0	0
Pain in extremity	286 (10.2%)	3 (0.1%)	NAb	325 (11.6%)	4 (0.1%)	NA ^b
Back pain	283 (10.1%)	10 (0.4%)	NAb	347 (12.4%)	9 (0.3%)	NAb
Рутехіа	279 (10.0%)	2 (0.1%)	0	127 (4.5%)	0	0

^aOne Grade 5 event occurred, ^bMax Grade 3 event (according to CTCAE v. 4), ^cMax Grade 2 event (according to CTCAE v. 4), Abbreviations: ET=endocrine therapy; n=number of patients; N=number of patients in population; NA=not applicable; PE=pulmonary embolism

□© Ann Oncol 2021

References

- Johnston, S. R. D., N. Harbeck, R. Hegg, M. et al. 2020. "Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer (monarchE)." J Clin Oncol 38(34):3987-3998.
- 2 Harbeck, N., P. Rastogi, M. Martin, et al. 2021. "Adjuvant abemaciclib combined with endocrine therapy for high-risk early breast cancer: updated efficacy and Ki-67 analysis from the monarchE study." Ann Oncol 32(12):1571-1581.

History

Version 1

Date	Summary of changes
05/08/2022	New protocol reviewed and approved at Medical Oncology Reference Committee meeting.
02/09/2022	Protocol published on eviQ. Review in 1 year.
08/02/2023	As per reference committee consensus terminating conditions changed from "2 years or until disease progression or unacceptable toxicity" to "2 years or until disease recurrence or unacceptable toxicity".

Breast adjuvant abemaciclib Page 9 of 10

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: 26 August 2022 **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/4168

07 Jun 2023

Breast adjuvant abemaciclib Page 10 of 10

Patient information - Breast cancer adjuvant - Abemaciclib



Patient's name:

Your treatment

It is important to understand that abemaciclib is not a traditional chemotherapy drug and has a different way of working. It works by targeting the cancer cells to stop them growing and spreading. The treatment schedule below explains how the drug for this treatment is given.

Abemaciclib				
This treatment is continuous for 2 years. Do not stop taking abemaciclib tablets without telling your doctor.				
Day	Day Treatment How it is given			
Continuous	Abemaciclib (uh-BEH-muh-SYE-klib)	Take orally TWICE a day at the same time each day, 12 hours apart. Swallow the tablets whole with a glass of water. Do not break, crush or chew. If you forget to take a dose or vomit a dose, take your normal dose the next time it is due. Do not take an extra dose.		

Abemaciclib is available as 50 mg, 100 mg and 150 mg tablets. It is important that you take the correct number of tablets and understand how to take them. Ask your doctor, nurse or pharmacist to complete the table below with the correct number of tablets for you:

Abemaciclib	Morning	Evening
50 mg tablets		
100 mg tablets		
150 mg tablets		

Abemaciclib is used in combination with hormonal therapy. Your doctor will discuss your treatment plan with you.

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 palpitations (fast and/or irregular heartbeat), dizziness or fainting 	Daytime: Night/weekend: Other instructions:
you become unwell.	

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

• Antidiarrhoeals: you may be given some medication to treat diarrhoea. Your doctor or nurse will tell you how and when to take your antidiarrhoeal medication.

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)

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.

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:
 - o 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.

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.

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.

Liver problems	 You may get: yellowing of your skin or eyes itchy skin 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.
Lung problems	 Lung problems are rare, but can be serious. They may occur throughout treatment or after the completion of treatment. You may get: shortness of breath fever dry cough wheezing fast heartbeat chest pain. Your doctor will monitor how well your lungs are working during your treatment. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have chest pain or become short of breath.

Late (onset weeks to months	
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)
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.
Blood clots (thromboembolism)	 Blood clots can occur with this 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: redness, heat or pain in your leg(s) numbness or weakness in your face, arm or leg chest pain sudden shortness of breath dizziness trouble speaking blurred vision severe headache unexplained falls or loss of balance.

General advice for people having cancer treatment

Blood clot risk

• Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).

- Tell your doctor if you have a family history of blood clots.
- · A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.
- If you have any of these symptoms go to your nearest hospital Emergency Department.

Medications and vaccinations

- Before you start treatment, tell your doctor about any medications you are taking, including vitamins or herbal supplements.
- Don't stop or start any medications during treatment without talking to your doctor and pharmacist first.
- 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.

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.

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.

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

Additional notes:	

This document is a guide only and cannot cover every possible situation. The health professionals caring for you should always consider your individual situation when making decisions about your care. Contact your cancer clinic staff or doctor if you have any questions or concerns about your treatment, or you are having problems coping with side effects. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use of this document is subject to eviQ's disclaimer available at www.eviQ.org.au

First approved: 26 August 2022 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/pi/4168

07 Jun 2023