

Breast metastatic anastrozole

ID: 1302 v.2 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 <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 metastatic palbociclib
- · Breast metastatic ribociclib

Treatment schedule - Overview

Drug	Dose	Route
Anastrozole	1 mg ONCE a day	PO

Continuous until disease progression or unacceptable toxicity

Drug status: Anastrozole is a PBS restricted benefit

Cost: ~ \$20 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		
Anastrozole	1 mg (P0)	ONCE a day

Continuous until disease progression or unacceptable toxicity

Indications and patient population

· Advanced breast cancer in post-menopausal women with oestrogen/progesterone-receptor-positive disease.

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Clinical information

Emetogenicity MINIMAL	No antiemetics should be routinely administered before treatment in patients without a history of nausea and vomiting. If patients experience nausea and/or vomiting, consider using the low antiemetic prophylaxis regimen.
Bone mineral density (BMD)	Baseline BMD and repeat as clinically indicated. Lifestyle modification including regular exercise, particularly weight bearing exercises should be encouraged.
Supplements	Consider daily oral supplements of at least calcium 500 mg and vitamin D 400 International Units for the duration of the therapy.
Oestrogen preparations	Oestrogen preparations should be avoided due to insufficient data on safety as systemic absorption of oestrogen may negate the effect of aromatase inhibitors. Minimal use of topical oestrogen therapies for vulvo-vaginal complaints may be considered.
Blood tests	LFTs, lipid studies, calcium and vitamin D at baseline and repeat as clinically indicated.
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.

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.

Renal impairment

No dose modifications necessary

Hepatic impairment				
Hepatic dysfunction				
Severe	Anastrozole has not been investigated in patients with severe hepatic impairment The potential risk / benefit to such patients should be carefully considered before administration of anastrozole			

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

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• Cytochrome P450 Drug Interactions

Anastrozole				
	Interaction	Clinical management		
Tamoxifen	Reduced efficacy of anastrozole due to lowered plasma levels	Combination contraindicated		
Oestrogen containing therapies	Negate the pharmacological action of anastrozole	Avoid combination (minimal use of topical oestrogen therapy for vulvo-vaginal complaints may be considered)		

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.

Administration

This is a continuous oral treatment

Safe handling and waste management (reproductive risk only)

Safe administration

Anastrozole

- administer orally ONCE a day
- · to be swallowed whole with a glass of water
- can be taken with food or on an empty stomach
- if nausea develops, anastrozole may be taken with or after food or at night.

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

Anastrozole tablets

• Anastrozole tablets with written instructions on how to take them.

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)		
Headache		
Nausea and vomiting		

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Early (onset days to weeks)				
Hot flushes				
Hyperlipidaemia and hypercholesterolaemia	Abnormally elevated levels of lipids and cholesterol in the blood.			
Fluid retention and oedema An excess amount of fluid around the cells, tissues or serous cavities of the body, leading to swelling.				
Late (onset weeks to months)				
Arthralgia and myalgia Generalised joint pain or and/or stiffness and muscle aches, often worse upon wakin long periods of inactivity. Can improve with movement. May be mild or severe, intern constant and accompanied by inflammation. Read more about arthralgia and myalgia				
Vaginal atrophy	Read more about vaginal dryness			
Delayed (onset months to years)				
Osteoporosis				

Evidence

The evidence supporting this protocol is provided by two multicentre international randomised, double-blind trials involving 1021 patients comparing anastrozole with tamoxifen alone as first-line therapy for advanced breast cancer in postmenopausal women.¹

Between February 1996 and July 1998, 340 patients were randomised to receive anastrozole 1 mg daily and 328 patients were randomised to receive tamoxifen 20 mg daily in the TARGET trial. Between August 1995 and July 1998, 171 patients were randomised to receive anastrozole 1 mg daily and 182 patients were randomised to receive tamoxifen 20 mg daily in the North American trial.¹

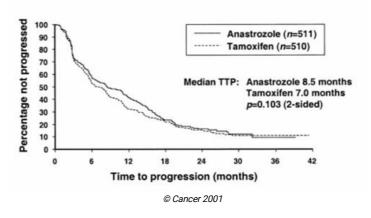
The primary objectives were time to treatment progression (TTP), objective response (OR) rate, and tolerability and secondary objectives were time to treatment failure (TTF), response duration, and clinical benefit duration.¹

Efficacy

After a median follow-up of 18.2 months, anastrozole was at least equivalent to tamoxifen in terms of median TTP (8.5 vs 7.0 months). In a retrospective subgroup analysis, anastrozole was superior to tamoxifen with respect to TTP (10.7 vs 6.4 months, p = 0.022) in patients with oestrogen and/or progesterone receptor positive tumours. 1.

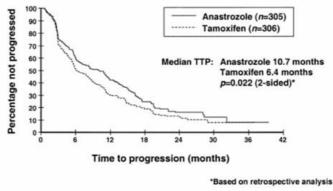
29.0% of anastrozole and 27.1% of tamoxifen patients achieved either a complete response (CR) or a partial response (PR). Clinical benefit rates were 57.1% and 52.0% for anastrozole and tamoxifen, respectively.

Kaplan-Meier plot of time to progression in patients receiving anastrozole 1 mg or tamoxifen 20 mg once daily.



Kaplan-Meier probability of time to progression in patients receiving anastrozole 1 mg or tamoxifen 20 mg once daily—subgroup of patients with ER+ and/or PgR+ tumors.

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Toxicity

Both anastrozole and tamoxifen were well tolerated. Anastrozole led to significantly fewer venous thromboembolic (P = 0.043; not adjusted for multiple comparisons) events, and vaginal bleeding was reported in fewer patients treated with anastrozole than with tamoxifen.¹

Toxicity¹

	Anastrozole 1 mg ($n = 506$)			Tamoxifen 20 mg ($n = 511$)					
	Irrespective of causality		Treatment-related		Irrespective of causality		Treatment-related		
Adverse event category	n	%	n	%	n	%	n	%	P value
Depression	23	4.5	2	0.4	32	6.3	2	0.4	0.2676
Tumor flare	15	3.0	7	1.4	18	3.5	12	2.3	0.7241
Thromboembolic disease Venous	18	3.6	3	0.6	33	6.5	7	1.4	0.0434
thromboembolism Coronary & cerebral	5	1.0	2	0.4	15	2.9	6	1.2	
thrombosis	13	2.6	1	0.2	19	3.7	2	0.4	
Gastrointestinal disturbance	170	33.6	55	10.9	196	38.4	62	12.1	0.1173
Nausea	94	18.6	42	8.3	106	20.7	50	9.8	
Vomiting	38	7.5	4	0.8	36	7.0	8	1.6	
Diarrhea	40	7.9	8	1.6	33	6.5	3	0.6	
Hot flushes	134	26.5	120	23.7	118	23.1	101	19.8	0.2176
Vaginal dryness	9	1.8	7	1.4	3	0.6	3	0.6	0.0890
Lethargy	6	1.2	3	0.6	15	2.9	6	1.2	0.0754
Vaginal bleeding ^b	5	1.0	2	0.4	11	2.2	8	1.6	0.2066
Weight gain	11	2.2	8	1.6	8	1.6	6	1.2	0.4975

^a P value for incidence of events irrespective of causality—not adjusted for multiple comparisons.

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References

Bonneterre, J., A. Buzdar, J. M. Nabholtz, et al. 2001. "Anastrozole is superior to tamoxifen as first-line therapy in hormone receptor positive advanced breast carcinoma." Cancer 92(9):2247-2258.

History

Version 2

Date	Summary of changes
27/04/2012	New protocol taken to Medical Oncology Reference Committee meeting.

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 $^{^{\}mathrm{b}}$ One and four additional patients in anastrozole and tamoxifen arms, respectively, had metrorrhagia.

Date	Summary of changes
14/06/2012	Approved and published on eviQ.
09/05/2014	Protocol reviewed by email survey. No change and next review in 2 years.
18/02/2016	Discussion with Medical Oncology Reference Committee Chairs and protocol to be reviewed every 5 years. Next review due in 3 years.
31/05/2017	Transferred to new eviQ website. Version number change to V.2.
11/12/2018	Related pages updated with link to ID 3379 Breast metastatic ribociclib
23/09/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 30/08/2019. ID 3369 Breast metastatic palbociclib added as related page. Next review in 5 years.
19/05/2022	'Not a traditional chemotherapy drug' statement added to patient information.

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

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Patient information - Breast cancer metastatic -**Anastrozole**



Patient's name:

Your treatment

It is important to understand that anastrozole is not a traditional chemotherapy drug and has a different way of working. It works by reducing hormones which stops the cancer cells growing and spreading. The treatment schedule below explains how the drug for this treatment is given.

Anastrozole This treatment is continuous. Your doctor will advise you how long to take the tablets for. Do not stop taking anastrozole tablets without telling your doctor.

Day	Treatment	How it is given
Continuous	Anastrozole (an-as-troe-zole)	Take orally ONCE a day at the same time each day, with or without food. If you forget to take a tablet or vomit a tablet, take your normal dose the next time it is due. Do not take an extra dose.

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 suddenly become unwell.

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IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you notice

any pain or swelling in your legs or arms or if you develop any sudden shortness of breath or chest pain **Emergency contact details** Ask your doctor or nurse from your treating team who to contact if you have a problem Daytime: Night/weekend: Other instructions:

Other information about your treatment

Changes to your dose or treatment delays

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

Blood tests and monitoring

You may need to have blood tests while you are receiving this treatment. Your doctor or nurse will tell you when to have these blood tests.

Hormonal cancer treatment

Certain types of breast cancer need oestrogen to grow. Anastrozole works by reducing the supply of oestrogen to these cancer cells.

You may notice some vaginal bleeding in the first few weeks of treatment. If the bleeding continues tell your doctor or nurse. Some people may experience hair thinning with this treatment. This is usually mild and rarely results in significant hair loss.

You must not take any medications that contain oestrogen while you are having treatment with anastrozole. This includes some oral contraceptives, hormone replacement therapy (HRT) and oestrogen creams. Ask your doctor or pharmacist for more

Other medications given during this treatment

• Calcium and vitamin D supplements: you may be given some calcium and vitamin D tablets. Your doctor or nurse will tell you how and when to take these.

Side effects

information.

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)			
Headache	 You can take paracetamol if you have a headache. Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get a very bad headache that is not helped by pain medication. 		
Nausea and vomiting	 You may feel sick (nausea) or be sick (vomit). 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. Anti-sickness medication is usually not needed but may help in some people. 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)	
Hot flushes	 You may get flushing of your face, sweating and sensations of heat. Avoid alcohol, coffee, tea and spicy foods, as they can make hot flushes worse. Wear lightweight clothes made from natural fibres; dress in layers. Put a cold, wet towel against your neck during hot flushes. Talk to your doctor or nurse about other ways to manage these symptoms.
High blood cholesterol levels	 This treatment may increase your blood cholesterol levels. This is not a side effect you will notice. Your cholesterol levels will be checked during your treatment.
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. 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 or gain 1 to 2 kg in a week. 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)				
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. 			
Vaginal changes	 You may get a dry vagina. This may cause pain or discomfort during sex. Use a vaginal moisturiser. Before sex use a water-based lubricating gel. Talk to your doctor or nurse about other ways to manage these symptoms. 			

Delayed (onset months to years)				
Weak and brittle bones (osteoporosis)	 Your bones may fracture easily and may become painful. You may have trouble moving around. You may find it hard to perform daily chores. Try to do some weight-bearing exercise for 30 minutes at least three times a week. Watch out for slippery floors and make sure walkways are well lit. Take calcium and vitamin D supplements if prescribed by your doctor. You may have regular tests to check your bones both before and during treatment. Tell your doctor or nurse if you get any of the signs or symptoms listed above. 			

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.
- Vaccinations such as flu and tetanus vaccines are safe to receive while you are having treatment. If you are unsure, check with your doctor before you have any vaccinations.

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.
- 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.

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

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