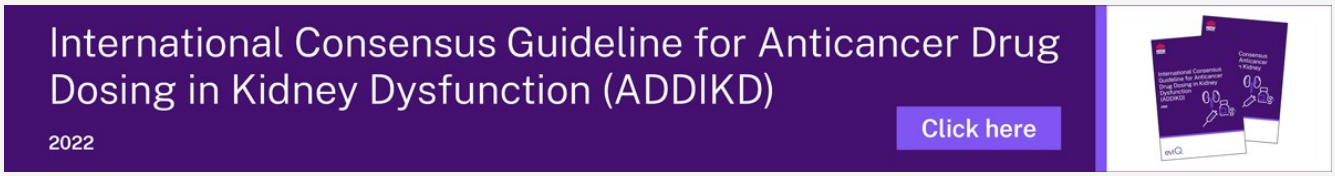
Breast metastatic exemestane

ID: 1304 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 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.



Treatment schedule - Overview

Drug	Dose	Route
Exemestane	25 mg ONCE a day	PO

Continuous until disease progression or unacceptable toxicity

Drug status: Exemestane is a PBS restricted benefit

Cost: ~ $60 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		
Exemestane	25 mg (PO)	ONCE a day with or after food

Continuous until disease progression or unacceptable toxicity

Indications and patient population

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

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	Use with caution

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*

Exemestane		
	Interaction	**Clinical management**
Oestrogen containing therapies	Negate the pharmacological action of exemestane	Combination contraindicated (minimal use of topical oestrogen therapy for vulvo-vaginal complaints may be considered)
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of exemestane possible due to increased clearance	Caution advised if combination used - monitor for decreased clinical response to exemestane

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

Exemestane

- administer orally ONCE a day
- to be swallowed whole with a glass of water; do not break, crush or chew
- to be taken with or immediately after food
- if nausea develops, take after food 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

Exemestane tablets

- Exemestane 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)	
Nausea and vomiting	
Headache	

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 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
Vaginal atrophy	Read more about vaginal dryness

Delayed (onset months to years)	
Osteoporosis	

Evidence

The evidence supporting this protocol is provided by a phase III, multicentre, randomised trial involving 769 patients comparing exemestane with megestrol acetate in postmenopausal women with progressive advanced breast cancer who experienced failure with tamoxifen.[1]

Between October 1995 and May 1998, 366 patients were randomised to receive exemestane 25 mg daily and 403 patients were randomised to receive megestrol 40 mg four times daily.[1]

The primary efficacy end point was OR rate and secondary end points included overall success rate, overall success duration, time to OR, duration of OR, duration of SD greater than or equal to 24 weeks, time to tumor progression (TTP), time to treatment failure (TTF), survival time, subjective response, and effects on circulating oestrogen levels.[1]

Efficacy

The overall objective response (OR) rates were higher in patients treated with exemestane than in those treated with megestrol (15.0% vs 12.4%). Median survival time was significantly longer with exemestane (median not reached) than with megestrol (123.4 weeks; P =0.039), as were the median duration of overall success (OR or stable disease > 24 weeks; 60.1 vs 49.1 weeks; P =0.025), time to tumor progression (20.3 vs 16.6 weeks; P =0.037), and time to treatment failure (16.3 vs 15.7 weeks; P = 0.042).[1]

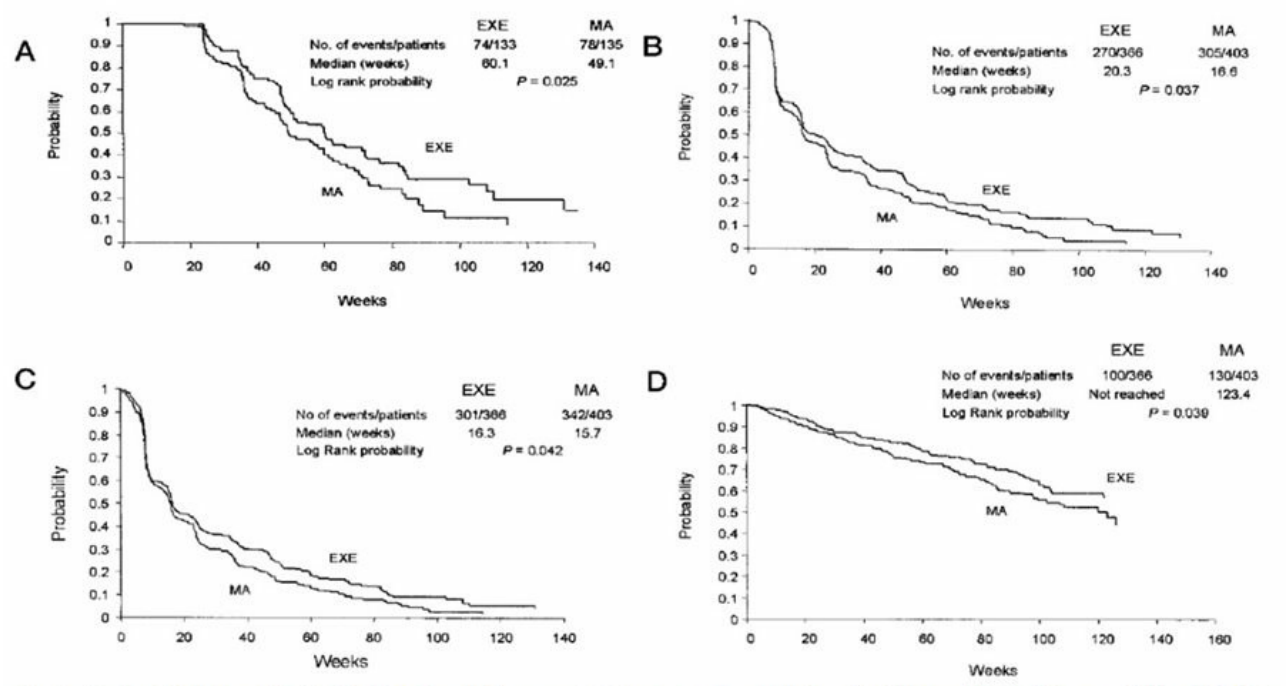


Fig 1. Kaplan-Meier curves for (A) duration of overall success, (B) time to tumor progression, (C) time to treatment failure, and (D) survival, in postmenopausal women with progressive advanced breast cancer after therapy with TAM and subsequently treated with EXE or MA.

Toxicity

Compared with megestrol, there were similar or greater improvements in pain, TRSS, and QOL with exemestane. Both drugs were well tolerated. Grade 3 or 4 weight changes were more common with megestrol (17.1% vs 7.6%; *P* = 0.001).[1]

Adverse events [1]

Table 4. Patients Reporting Selected Adverse Events of Drug-Related or Indeterminate Cause

Event	EXE (n = 358) No. of Patients	EXE (n = 358) %	MA (n = 400) No. of Patients	MA (n = 400) %	Odds Ratio (EXE/MA)	95% CI
Any adverse event	140	39.1	183	45.8	0.76	0.57-1.02
Hot flashes*	45	12.6	20	5.0	2.73	1.58-4.72†
Nausea*	33	9.2	20	5.0	1.93	1.09-3.43†
Fatigue*	27	7.5	41	10.3	0.71	.43-1.19
Increased sweating*	16	4.5	30	7.5	0.58	.31-1.08
Insomnia*	13	3.6	13	3.3	1.12	.51-2.45
Dizziness*	12	3.4	12	3.0	1.12	.50-2.53
Increased appetite	10	2.8	23	5.8	0.47	.22-1.00
Abdominal pain*	10	2.8	17	4.3	0.65	.29-1.43
Vomiting	10	2.8	3	0.8	3.80	1.04-13.93†
Rash	7	2.0	0	0		
Constipation	3	0.8	10	2.5	0.33	.09-1.21
Dyspnea	1	0.3	12	3.0	0.09	.01-0.70†

*Elicited adverse events (patients specifically asked about these adverse events).
†Interval does not include 1.

References

1 Kaufmann, M., E. Bajetta, L. Y. Dirix, et al. 2000. "Exemestane is superior to megestrol acetate after tamoxifen failure in postmenopausal women with advanced breast cancer: results of a phase III randomized double-blind trial. The Exemestane Study Group." J Clin Oncol 18(7):1399-1411.

History

Version 2

Date	Summary of changes
27/04/2012	New protocol taken to Medical Oncology Reference Committee meeting.
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.
23/09/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 30/08/2019. No changes. Next review in 5 years.
15/12/2021	Removed antiemetic block from clinical information as nil required.
19/05/2022	Antiemetic clinical information block added to align with other breast endocrine protocols. 'Not a traditional chemotherapy drug' statement added to patient information.

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https://www.eviq.org.au/p/1304
07 Jun 2023

Patient information - Breast cancer metastatic - Exemestane

Patient's name:

Your treatment

It is important to understand that exemestane 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.

Exemestane		
This treatment is continuous. Your doctor will advise you how long to take this treatment for. Do not stop taking exemestane tablets without telling your doctor.		
Day	**Treatment**	**How it is given**
Continuous	**Exemestane** (*EX-e-MES-tane)*	Take orally ONCE a day, at the same time each day, after food. Swallow tablets whole with a glass of water, do not break, crush or chew. 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.

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. This treatment works by reducing the supply of oestrogen to these cancer cells.
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 this treatment. This includes some oral contraceptives, hormone replacement therapy (HRT) and oestrogen creams. Ask your doctor or pharmacist for more information.

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

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). • 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.**
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.**

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:

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