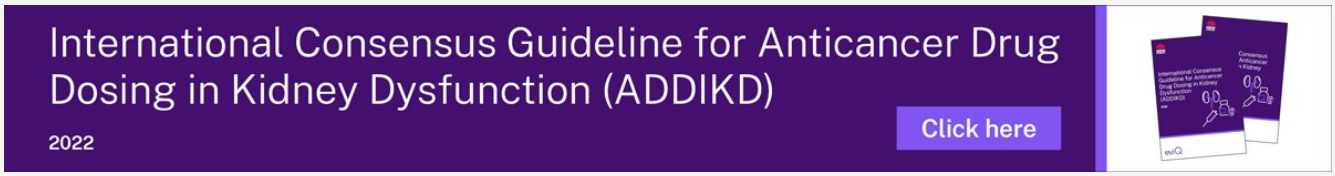
Breast metastatic goserelin

ID: 1315 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.



Related pages:

- Breast metastatic tamoxifen
- Breast metastatic anastrozole
- Breast metastatic letrozole
- Breast metastatic exemestane

Treatment schedule - Overview

Cycle 1 and further cycles

Drug	Dose	Route	Day
Goserelin	3.6 mg	Subcut	1

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

Notes:
Goserelin can be used in combination with tamoxifen or aromatase inhibitors (AIs)

Drug status: Goserelin is a PBS restricted benefit

Cost: ~ $220 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.*

Cycle 1 and further cycles

Day 1

Day 1		
Goserelin	3.6 mg (Subcut)	inject subcutaneously into the upper anterior abdominal wall

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

Indications and patient population

- Locally advanced or metastatic breast cancer in pre-menopausal women suitable for hormonal manipulation

Clinical information

Tumour flare	Goserelin can cause short-term (2 to 3 weeks) stimulation of oestradiol prior to luteinising hormone-releasing hormone (LHRH) down regulation, which may cause new or worsening signs and symptoms of breast cancer e.g. increased bone pain.
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.
Blood tests	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.
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. Hormonal methods of birth control should not be used during this treatment. 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 .

Renal impairment

Renal impairment
No dose modifications necessary

Hepatic impairment
No dose modifications necessary

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*

Goserelin		
	Interaction	**Clinical management**
Drugs that may prolong the QTc interval (e.g. azole antifungals, tricyclic antidepressants, antiarrhythmics etc.)	Additive effect with goserelin; may lead to torsades de pointes and cardiac arrest	Avoid combination or minimise additional risk factors (e.g. correct electrolyte imbalances) and monitor ECG for signs of cardiac arrhythmia

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

Subcutaneous injection

Safe handling and waste management (reproductive risk only)

Safe administration

Treatment - Time out

Goserelin SafeSystem™ implant

- administer goserelin as a subcutaneous injection into the anterior abdominal wall (below the umbilicus):
  - apply local anaesthetic (e.g. EMLA®, LMX4®, lignocaine 1%) to the injection site (if indicated) and wait for it to take effect. An ice pack with no local anaesthetic may also be used
  - wipe residual topical anaesthetic cream from chosen injection site (if used).

For correct administration of Zoladex®, refer to the instructions supplied with the product:

- put patient in a comfortable position with upper body slightly raised
- swab abdominal injection site below the navel line
- open pouch at the arrows and remove syringe
- hold the syringe at a slight angle to the light

- check that at least part of the goserelin implant is visible
- grasp the plastic safety tab and pull away from the syringe and discard
- remove the needle cover. Unlike liquid injections, there is no need to remove air bubbles and attempts to do so may displace the implant
- hold the syringe around the protective sleeve
- pinch the patient's skin and insert the needle at a slight angle 30 to 45 degrees to the skin, with the opening of the needle facing up, until the protective sleeve touches the patient's skin
- do not penetrate into muscle or peritoneum
- to discharge goserelin implant and to activate the protective sleeve, depress the plunger until you cannot depress it any further. If the plunger is not depressed fully the protective sleeve will NOT activate. You may hear a click and will feel the protective sleeve automatically begin to slide to cover the needle.
- withdraw the needle and allow the protective sleeve to continue to slide and cover the needle
- rotate the injection site each time to avoid soreness at any one site.

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

Discharge information

Supplements

- Daily oral supplements of calcium 500 mg and vitamin D 400 International Units are recommended.

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	

Early (onset days to weeks)	
Hot flushes	
Tumour flare reaction	An increase in bone and/or tumour pain, associated with a transient increase in tumour size. This may occur after initiation with hormonal treatment.
Fluid retention and oedema	An excess amount of fluid around the cells, tissues or serous cavities of the body, leading to swelling.
Hyperlipidaemia and hypercholesterolaemia	Abnormally elevated levels of lipids and cholesterol in the blood.

Late (onset weeks to months)	
Vaginal atrophy	Read more about vaginal dryness
Reduced libido and sexual dysfunction	Lowered sexual desire as well as any physical or psychological problem that interferes with the ability to have and/or enjoy sex.

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.
Osteoporosis	

Evidence

The evidence supporting this protocol is provided by a multicentre, randomised trial involving 136 patients comparing goserelin with surgical ovariectomy in premenopausal patients with receptor-positive metastatic breast cancer.[1]

Between August 1987 and July 1995, 69 patients were randomised to receive goserelin 3.6 mg SC depot every 4 weeks and 67 patients were randomised to undergo ovariectomy. For patients receiving goserelin, the dose could be increased to goserelin 7.2 mg every 4 weeks if after 8 weeks the patient had not become amenorrhoeic. Patients in the ovariectomy arm were offered crossover if there was clear progression at least 6 weeks following surgery.[1]

The primary objectives were failure-free survival (FFS) and overall survival (OS) and the secondary objectives were objective response rates and toxicity. The study was designed as an equivalence trial and because of slow accrual, it was terminated early, resulting in a final power of 60%.[1]

Efficacy

FFS and OS were similar for goserelin and ovariectomy. The goserelin to ovariectomy death hazards ratio was 0.80 and the associated 95% confidence interval (CI) was 0.53 to 1.20. The test of 50% improvement in survival due to ovariectomy was rejected at P =0.006. Goserelin lowered serum oestradiol to postmenopausal levels[1].

Kaplan-Meier analysis of (A) Failure-free survival (FFS) and (B) Overall survival (OS)[1]

(A)

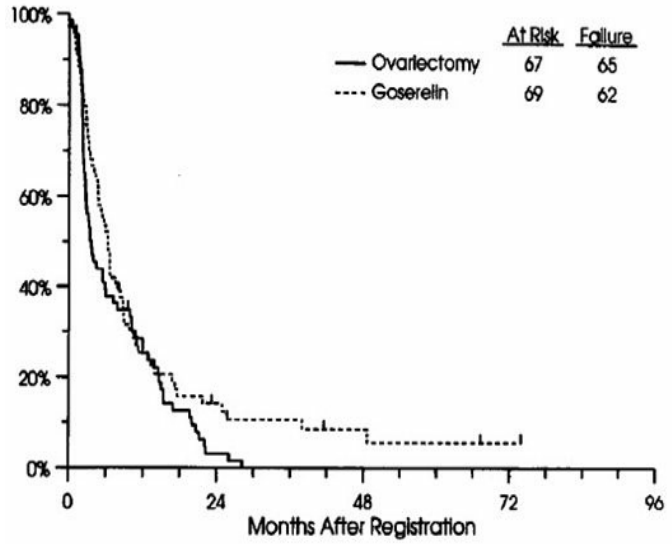


Fig 1. FFS by treatment arm.

(B)

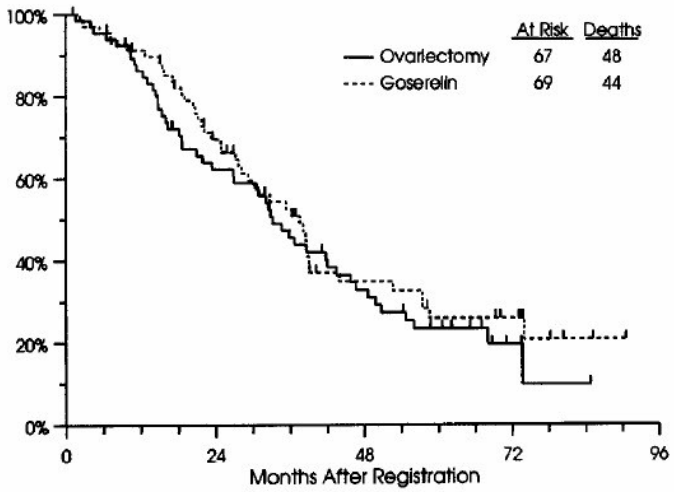


Fig 2. OS by treatment arm.

Toxicity

Hot flashes (75% vs 46%) and tumour flare (16% vs 3%) were more common with goserelin.[1]

Toxicity[1] Grade 1 and 2 (> 5% patients)	Goserelin (n=68) %	Ovariectomy (n=65) %
Hot flashes	66	43
Tumour flare	16	3
Bone pain	6	3
Leukopenia	9	2
Nausea	10	6
Oedema	7	0
Malaise	6	2

Toxicity[1] Grade 1 and 2 (> 5% patients)	Goserelin (n=68) %	Ovariectomy (n=65) %
Sweats	6	3
Vomiting	3	6

References

1 Taylor, C. W., S. Green, W. S. Dalton, et al. 1998. "Multicenter randomized clinical trial of goserelin versus surgical ovariectomy in premenopausal patients with receptor-positive metastatic breast cancer: an intergroup study." J Clin Oncol 16(3):994-999.

History

Version 2

Date	Summary of changes
27/04/2012	New protocol taken to Medical Oncology Reference Committee meeting.
12/06/2012	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.

First approved: 12 June 2012
Last reviewed: 30 August 2019
Review due: 31 December 2024

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https://www.eviq.org.au/p/1315
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Patient information - Breast cancer metastatic - Goserelin

Patient's name:

Your treatment

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

Goserelin			
This treatment cycle is repeated every 28 days. Your doctor will advise you how long you will have the treatment for.			
Day	**Treatment**	**How it is given**	**How long it takes**
1	**Goserelin** (*GOE-se-REL-in*)	By injection under the skin of your stomach. You may develop bruising around the site of the injection, this will fade over time.	About 5 minutes

When to get help

Emergency contact details

Ask your doctor or nurse from your treating team when you should get help and 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.

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)	
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.
Tumour flare reaction	• At the beginning of your treatment you may get: ◦ pain coming from the tumour ◦ bone and joint pain ◦ difficulty passing urine (patients with prostate cancer). • These symptoms are temporary and will go away after a few weeks. • 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. • 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.**
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.

Late (onset weeks to months)	
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.
Low sex drive	• This treatment lowers the amount of sex hormone in your body. • You may lose interest in sex, or have trouble having sex. • Talk to your doctor or nurse about ways to manage these symptoms.

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.
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.

Fertility

- Some cancer treatments can reduce your fertility. This can make it difficult or impossible to get pregnant.
- 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. Hormonal contraception (such as pills, injections or patches) should not be used in women having this 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

Additional notes:

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