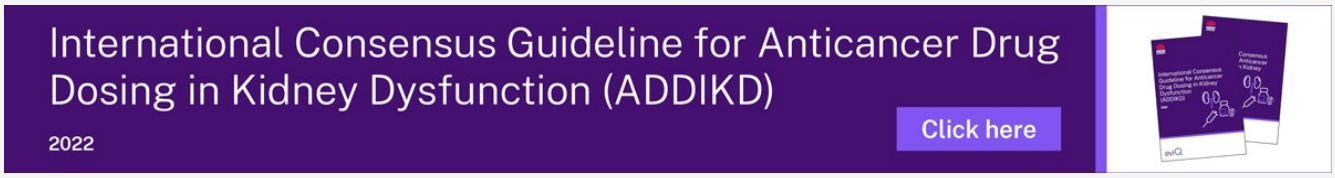
Prostate locally advanced or metastatic degarelix

ID: 818 v.3 **Endorsed**

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:

- Androgen deprivation therapy (ADT) for prostate cancer

Treatment schedule - Overview

Cycle 1

Drug	Dose	Route	Day
Degarelix	240 mg	Subcut	1

Cycle 2 and further cycles

Drug	Dose	Route	Day
Degarelix	80 mg	Subcut	1

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

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Drug status: **Degarelix (Firmagon®)** is PBS authority

Cost: ~ $360 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

Day 1		
Degarelix	240 mg (Subcut)	(starting dose) administered as two subcutaneous injections of 120 mg

Cycle 2 and further cycles

Day 1		
Degarelix	80 mg (Subcut)	(maintenance dose) administered as a single subcutaneous injection

Frequency: 28 days

Cycles: Continuous until disease progression or unacceptable toxicity

Indications and patient population

- Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostate cancer

Clinical information

Injection site reactions	This treatment has been associated with a high rate of injection site reactions (pain, erythema, swelling etc.) These reactions occurred more frequently with the starting dose and were transient and mostly mild to moderate.
Cardiovascular Risk	There may be a relation between androgen deprivation therapy (ADT) and cardiovascular events and death. The metabolic effects of ADT (increased body weight and abdominal girth, increased cholesterol and triglycerides, hyperinsulinaemia) may contribute to cardiovascular risk. Monitoring of blood pressure, lipid profile and blood glucose is recommended.
Bone mineral density (BMD)	Baseline BMD and repeat as clinically indicated. Lifestyle modification including regular exercise, particularly weight bearing exercises should be encouraged.
Blood tests	Lipid studies, calcium and vitamin D at baseline and repeat as clinically indicated. PSA and testosterone levels 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 .

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).

Renal impairment
No dose modification in mild to moderate renal impairment No studies done in severe renal impairment

Hepatic impairment
No dose modification in mild to moderate hepatic impairment No studies done in severe hepatic impairment

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*

Degarelix		
	Interaction	**Clinical management**
Drugs that may prolong the QTc interval (e.g. azole antifungals, tricyclic antidepressants, antiarrhythmics etc.)	Additive effect with degarelix; 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

Treatment - Time out

Degarelix

- reconstitute this drug as per manufacturers instructions with the recommended diluent
- administer immediately after reconstitution
- via deep subcutaneous injection
- before injecting, gently pull back the plunger to check if blood is aspirated if blood appears in the syringe, the reconstituted product can no longer be used
- discontinue the procedure and discard the syringe and needle (reconstitute a new dose for the patient)
- rotate the injection site each time
- do not massage or rub the injection site as this may disperse the depot resulting in altered release, avoid areas where the injection site is exposed to pressure i.e. waistband, rib area.

Discharge information

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)	
Flu-like symptoms	

Early (onset days to weeks)	
Hot flushes	
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
Fatigue	Read more about fatigue
Constipation	

Late (onset weeks to months)	
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.
Gynaecomastia	Enlargement of male breast tissue usually due to hormone imbalance or hormone therapy

Delayed (onset months to years)	
Osteoporosis	
Risk of coronary artery disease	

Evidence

The evidence supporting this protocol comes from a 12-month, open-label, multi-centre, randomised phase III study comparing degarelix, a gonadotrophin-releasing hormone (GnRH) antagonist vs leuprorelin in achieving and maintaining testosterone suppression.[1]

A total of 620 patients were randomised to one of the following 3 regimens:

1. Degarelix SC 240 mg (starting dose) for 1 month, followed by 80 mg monthly
2. Degarelix SC 240 mg (starting dose) for 1 month, followed by 160 mg monthly
3. Leuprorelin IM 7.5 mg monthly

The primary endpoint of the trial was suppression of testosterone to less than 0.5 ng/mL which was measured monthly.

Efficacy

Suppression of testosterone was achieved by 97.2%, 98.3% and 96.4% of patients in the degarelix 240/80 mg, degarelix 240/160 mg and the leuprorelin groups respectively. The median PSA levels at 14 and 28 days were significantly lower in the degarelix groups than in the leuprorelin group (P<0.001).[1]

TABLE 3 Testosterone response rates (i.e. cumulative probability of a testosterone level of ≤0.5 ng/mL from 28 to 364 days: Kaplan–Meier estimates of individual response rates; ITT analysis set)

	n	n Responders	% (95% CI)
Degarelix 240/80 mg s.c.	207	202	97.2 (93.5–98.8)
Degarelix 240/160 mg s.c.	202	199	98.3 (94.8–99.4)
Leuprolide 7.5 mg i.m.	201	194	96.4 (92.5–98.2)

n, number of dosed patients; Responder, testosterone ≤0.5 ng/mL at 28–364 days; %, Kaplan–Meier estimated response rates.

Toxicity

The side effects of the three treatment groups were similar to previously reported effects for androgen-deprivation therapy. SC Degarelix was associated with a higher rate of injection-site reactions than with IM leuprorelin (40% vs < 1%; P<0.001). There were additional differences between the degarelix and leuprorelin groups for urinary tract infections (3% vs 9%; P<0.01), arthralgia (4% vs 9%; P<0.05) and chills (4% vs 0%; P<0.01).[1]

Cardiovascular side effects were reported by 13% and 9% of patients in the leuprorelin and degarelix groups respectively.[1]

There is currently no safety data on degarelix beyond 12 months and so the long term effects (cardiovascular complications and effects on bone mineral density) is not known.

TABLE 4 Incidence and intensity of treatment-emergent AEs (≥5% in any group)

	Degarelix			
AE, *n* (%)	240/80 mg	240/160 mg	Pooled	Leuprolide 7.5 mg
ITT analysis set	207	202	409	201
Any	163 (79)	167 (83)	330 (81)	156 (78)
Injection-site reaction§	73 (35)	89 (44)	162 (40)	1 (<1)†
Hot flush	53 (26)	52 (26)	105 (26)	43 (21)
ALT increase	20 (10)	17 (8)	37 (9)	11 (5)
Weight increase	18 (9)	22 (11)	40 (10)	24 (12)
Back pain	12 (6)	12 (6)	24 (6)	17 (8)
Hypertension	12 (6)	14 (7)	26 (6)	8 (4)
AST increase	10 (5)	11 (5)	21 (5)	6 (3)
Arthralgia	11 (5)	6 (3)	17 (4)	18 (9)*
UTI	10 (5)	3 (1)	13 (3)	18 (9)†
Fatigue	7 (3)	13 (6)	20 (5)	13 (6)
Hypercholesterolaemia	7 (3)	12 (6)	19 (5)	5 (2)
Chills	7 (3)	11 (5)	18 (4)	0†
Constipation	6 (3)	11 (5)	17 (4)	10 (5)
Intensity				
Any	163 (79)	167 (83)	330 (81)	156 (78)
Mild	138 (67)	145 (72)	283 (69)	138 (69)
Moderate	113 (55)	112 (55)	225 (55)	101 (50)
Severe	32 (15)	36 (18)	68 (17)	26 (13)
Life threatening	1 (<1)	2 (<1)	3 (<1)	5 (2)
Death¶	5 (2)	5 (2)	10 (2)	9 (4)

*Statistically significant differences between the pooled degarelix and leuprolide groups, *P < 0.05, †P < 0.01, and ‡P < 0.001. §Injection-site reactions include injection-site pain, erythema, swelling, induration, and nodule. ¶None of the deaths was considered related to study treatment. AEs were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events [17].*

References

1 Klotz, L., L. Boccon-Gibod, N. D. Shore, et al. 2008. "The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer." BJU Int 102(11):1531-1538.

History

Version 3

Date	Summary of changes
22/10/2010	New protocol taken to Medical Oncology Reference Committee meeting.
18/11/2010	Approved and published on eviQ.
22/02/2011	New format to allow for export of protocol information.

Date	Summary of changes
	Protocol version number changed to *V.2.* Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations.
8/12/2011	Updated PHC view.
30/11/2012	Protocol reviewed at Medical Oncology Reference Committee meeting. No changes and next review in 2 years.
09/05/2014	Protocol reviewed by Medical Oncology Reference Committee meeting electronically; no changes. PHC view removed. Review 2 years.
31/03/2017	Protocol discussed and decided to have a 5 year review period. Next due for review in 2019.
31/05/2017	Transferred to new eviQ website. Protocol version number changed to V.3.
30/11/2017	Link to Androgen Deprivation Therapy (ADT) patient information sheet added to protocol and patient information.
25/03/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 15/03/2019. No changes. Next review in 5 years.

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https://www.eviq.org.au/p/818
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Patient information - Prostate cancer locally advanced or metastatic - Degarelix

Patient's name:

Your treatment

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

Degarelix			
This treatment cycle is repeated every 28 days. Your doctor will advise you of the number of treatments you will have.			
Day	**Treatment**	**How it is given**	**How long it takes**
1	**Degarelix** (*deg-a-REL-ix*)	By injection under the skin of your stomach	About 5 minutes

When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you suddenly become unwell.

IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse 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: .....

.....

.....

.....

You may develop bruising around the injection site, this will fade over time. If you have any concerns about this tell your doctor or nurse.

Other information about your treatment

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.

Androgen deprivation therapy (ADT)

For more information see the eviQ patient information sheet on Androgen deprivation therapy (ADT) for prostate cancer.

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)	

Flu-like symptoms	• You may get:
	  ◦ a fever
	  ◦ chills or sweats
	  ◦ muscle and joint pain
	  ◦ a cough
	  ◦ headaches.
	• Tell your doctor or nurse if you get any of the symptoms listed above.
	• **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have a temperature of 38°C or higher.**

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.
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.
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.**

Constipation	• You may have bowel motions (stools, poo) that are less frequent, harder, smaller, painful or difficult to pass.
	• You may also get:
	  ◦ bloating, cramping or pain
	  ◦ a loss of appetite
	  ◦ nausea or vomiting.
	• Drink plenty of fluids (unless you are fluid restricted).
	• Eat plenty of fibre-containing foods such as fruit, vegetables and bran.
	• Take laxatives as directed by your doctor.
	• Try some gentle exercise daily.
	• **Tell your doctor or nurse if you have not opened your bowels for more than 3 days.**

Late (onset weeks to months)	
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.
Breast tissue enlargement in men (gynaecomastia)	• You may get swelling and tenderness in the breast area. • This is not harmful but may be upsetting to some men.

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.
Heart problems and high blood pressure	• You may get: ◦ chest pain ◦ shortness of breath ◦ an abnormal heartbeat ◦ swelling in your hands, arms, legs and feet • If you have a history of high blood pressure, heart disease or stroke, tell your doctor. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the 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 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.

Fathering a child

- Some cancer treatments can be dangerous to unborn babies. Talk to your doctor or nurse if you think there is any chance that your partner could be pregnant.
- Do not try to 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 fatherhood after completing this treatment, talk to your doctor. Some doctors advise waiting between 6 months and 2 years after treatment.

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

Prostate cancer information

- Continence Foundation of Australia – continence.org.au
- Healthy Male Andrology Australia – healthymale.org.au
- National Continence Management Strategy – bladderbowel.gov.au/ncp/ncms
- National Public Toilet Map – toiletmap.gov.au
- Prostate Cancer Foundation of Australia – prostate.org.au
- South Australian Prostate Cancer Clinical Outcome Collaborative – prostatehealth.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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