

**DRUG NAME: Degarelix****SYNONYM(S):****COMMON TRADE NAME(S):** FIRMAGON®**CLASSIFICATION:** hormonal agent*Special pediatric considerations are noted when applicable, otherwise adult provisions apply.***MECHANISM OF ACTION:**

Degarelix is a gonadotropin-releasing hormone (GnRH) receptor antagonist. Degarelix immediately, competitively, and reversibly binds to and blocks GnRh receptors in the pituitary, which reduces the release of luteinizing hormone, follicle stimulating hormone, and consequently testosterone without causing an associated testosterone surge or clinical flare. Testosterone suppression occurs immediately after administration in 96% of patients. Co-administration of anti-androgens is not necessary for surge protection.<sup>1,2</sup>

**USES:****Primary uses:**

\*Prostate cancer

\*Health Canada approved indication

**Other uses:****SPECIAL PRECAUTIONS:**

- Degarelix is not intended for use in women.<sup>1</sup>
- Mild/moderate hypertension, QT/QTc prolongation, and myocardial infarction are reported with degarelix. Screening for and treatment of cardiovascular disease is suggested. ECG and serum electrolytes are suggested baseline tests to be ordered prior to treatment. Drug interactions should be considered during concomitant therapy with products known to prolong the QTc interval or induce torsades de pointes.<sup>1</sup>
- Mild transient increases in ALT and AST, not accompanied by rises in bilirubin or clinical symptoms, are reported. Liver function should be monitored in known or suspected hepatic dysfunction.<sup>1</sup>

**SIDE EFFECTS:**

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials. When placebo-controlled trials are available, adverse events are included if the incidence is  $\geq 5\%$  higher in the treatment group.

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in <b><i>bold, italics</i></b>	
blood and lymphatic system/ febrile neutropenia	anemia (3%)
cardiac (see also: investigations)	<b><i>atrio-ventricular first degree block</i></b>
	<b><i>hypertension</i></b> (6-7%)
	<b><i>myocardial infarction</i></b> (1%)
	vaso-vagal reaction
gastrointestinal	<b><i>emetogenic potential: rare</i></b> <sup>3</sup>
	constipation (3-5%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in <b>bold, italics</b>	
	diarrhea ( $\geq 1\%$ )
	nausea (1-5%) <sup>1,4</sup>
general disorders and administration site conditions	<b>extravasation hazard: none</b> <sup>5</sup>
	chills (3-5%); transient, occurring within hours of dosing
	fatigue (3-6%)
	fever (1-5%); transient, occurring within hours of dosing
	influenza-like illness (1%); transient, occurring within hours of dosing
	<b>injection site reactions</b> (35-44%, severe <2%), including pain (28%), erythema (17%), swelling (6%), nodule (3%), or induration (4%); primarily with starting dose, transient
immune system	antidegarelix antibody formation (10%); clinical significance unknown, safety and efficacy appear unaffected <sup>1</sup>
	hypersensitivity (<1%)
injury, poisoning, and procedural complications	fracture (<1%)
investigations	<b>gamma-glutamyltransferase, increase</b> (10%, severe <1%); reversible
	hypercholesterolemia (3-6%)
	<b>QT/QTc interval prolongation</b> (20%)
	<b>serum transaminases, increase</b> (5-10%, severe <1%) <sup>1,4</sup> ; reversible
	<b>weight gain</b> (7-11%)
musculoskeletal and connective tissue	arthralgia (3-5%)
	asthenia (1-5%)
	back pain (6%)
	osteoporosis or osteopenia (3%)
nervous system	dizziness (1-5%)
	headache (1-5%)
	insomnia (1-5%)
renal and urinary	urinary tract infection (1-5%)
	urgency, frequency
reproductive system and breast disorders	erectile dysfunction, <b>impotence</b> (90%) <sup>6,7</sup>
	gynecomastia ( $\geq 1\%$ )
	<b>libido, decrease</b> (100%) <sup>6,7</sup>
	testicular atrophy ( $\geq 1\%$ )
skin and subcutaneous tissue	hyperhidrosis ( $\geq 1\%$ )
	urticaria
vascular	<b>hot flashes</b> (25-26%)
	night sweats (1-5%)

Adapted from standard reference<sup>1</sup> unless specified otherwise.

**SUPPLY AND STORAGE:**

**Injection:** Ferring Pharmaceuticals supplies degarelix for injection as 80 and 120 mg vials of powder for reconstitution in self-contained treatment packs, a treatment starter pack and a treatment maintenance pack. Kits also contain single use vials of sterile water for reconstitution. Store at room temperature. Do not shake. Keep vials upright at all times, including during reconstitution.<sup>1</sup>

**For basic information on the current brand used at the BC Cancer Agency, see [Chemotherapy Preparation and Stability Chart](#) in Appendix.**

**SOLUTION PREPARATION AND COMPATIBILITY:**

**For basic information on the current brand used at the BC Cancer Agency, see [Chemotherapy Preparation and Stability Chart](#) in Appendix.**

**Additional information:** reconstitution directions should be carefully followed for each kit to ensure delivery of correct dose.<sup>1</sup>

**Compatibility:** consult detailed reference

**PARENTERAL ADMINISTRATION:**

	BCCA administration guideline noted in <b><i>bold, italics</i></b>
<b><i>Subcutaneous</i></b>	depot injection <sup>1,8</sup>
Intramuscular	no information found
Direct intravenous	not recommended <sup>1</sup>
Intermittent infusion	not recommended <sup>1</sup>
Continuous infusion	no information found
Intraperitoneal	no information found
Intrapleural	no information found
Intrathecal	no information found
Intra-arterial	no information found
Intravesical	no information found

**DOSAGE GUIDELINES:**

Refer to protocol by which patient is being treated.

**Adults:**

BCCA usual dose noted in ***bold, italics***

*Subcutaneous:*<sup>1,8</sup>                      Cycle Length:  
 1 month:                      ***starting dose: 240 mg SC (as two injections of 120 mg) on day 1, followed by maintenance dose: 80 mg SC (as a single injection) monthly, starting one month after starting dose.***

Injections should be given in the abdominal region.

BCCA usual dose noted in ***bold, italics***

<i>Dosage in renal failure:</i>	Cycle Length: no adjustment required with mild to moderate impairment; not studied in severe impairment <sup>1</sup>
<i>Dosage in hepatic failure:</i>	no adjustment required with mild to moderate impairment; not studied in severe impairment <sup>1</sup>

**REFERENCES:**

1. Ferring Pharmaceuticals. FIRMAGON® product monograph. North York, Ontario; 06 November 2009.
2. McEvoy GK, editor. AHFS 2010 Drug Information. Bethesda, Maryland: American Society of Health-System Pharmacists, Inc. p. 1020-1021.
3. BC Cancer Agency. (SCNAUSEA) Guidelines for Prevention and Treatment of Chemotherapy-induced Nausea and Vomiting in Adults. Vancouver, British Columbia: BC Cancer Agency; 1 May 2009.
4. Basow DS editor. Degarelix. UpToDate 18.1 ed. Waltham, Massachusetts: UpToDate®; 2010.
5. BC Cancer Agency Provincial Systemic Therapy Program. Provincial Systemic Therapy Program Policy III-20: Prevention and Management of Extravasation of Chemotherapy. Vancouver, British Columbia: BC Cancer Agency; 01 December 2007.
6. Kim Chi MD. Personal communication. BC Cancer Agency Genitourinary Tumour Group; 25 August 2010.
7. Ian Harper. Personal communication. Medical Science Liaison Ferring Pharmaceuticals; 25 August 2010.
8. BC Cancer Agency Genitourinary Tumour Group. (GUPLHRHA) BCCA Protocol Summary for Therapy for Advanced Prostate Cancer Using LHRH Antagonist Degarelix. Vancouver, British Columbia: BC Cancer Agency; 1 July 2010.