Goserelin: Drug information

(For additional information see "Goserelin: Patient drug information")

For abbreviations and symbols that may be used in Lexicomp (show table)

Brand Names: US

Zoladex

Brand Names: Canada

Zoladex; Zoladex LA

Pharmacologic Category

Antineoplastic Agent, Gonadotropin-Releasing Hormone Agonist; Gonadotropin Releasing Hormone Agonist

Dosing: Adult

US labeling:

Prostate cancer, advanced: Males: SubQ:

28-day implant: 3.6 mg every 28 days

12-week implant: 10.8 mg every 12 weeks

Prostate cancer, stage B2 to C (in combination with an antiandrogen and radiotherapy; begin 8 weeks prior to radiotherapy): Males: SubQ:

Combination 28-day/12-week implant: 3.6 mg implant, followed in 28 days by 10.8 mg implant

28-day implant (alternate dosing): 3.6 mg; repeated every 28 days for a total of 4 doses

Breast cancer, advanced: Females: SubQ: 3.6 mg every 28 days

Endometriosis: Females: SubQ: 3.6 mg every 28 days for 6 months

Endometrial thinning: Females: SubQ: 3.6 mg every 28 days for 1 or 2 doses

Canadian labeling:

Prostate cancer, advanced: Males: SubQ:

28-day implant: 3.6 mg every 28 days

3-month implant: 10.8 mg every 13 weeks

Prostate cancer, stage B2 to C (in combination with an antiandrogen and radiotherapy; begin 8 weeks prior to radiotherapy): Males: SubQ:

Combination 28-day/3-month implant: 3.6 mg implant, followed in 28 days by 10.8 mg implant

28-day implant (alternate dosing): 3.6 mg; repeated every 28 days for a total of 4 doses

Breast cancer, advanced: Females: SubQ: 3.6 mg every 28 days

Breast cancer, early: Females: SubQ: 3.6 mg every 28 days

Endometriosis: Females: SubQ:

28-day implant: 3.6 mg every 28 days for 6 months

3-month implant: 10.8 mg every 12 weeks for 6 months

Endometrial thinning: Females: SubQ: 3.6 mg every 28 days for 2 doses

Off-label dosing:

Prevention of early menopause during chemotherapy for early stage hormone receptor negative breast cancer (off-label use): Adult females: SubQ: 3.6 mg every 28 days starting 1 week prior to the first chemotherapy dose; continue until within 2 weeks before or after the final chemotherapy dose (Moore, 2015).

Dosing: Geriatric

Males: Refer to adult dosing.

Dosing: Renal Impairment

No dosage adjustment necessary.

Dosing: Hepatic Impairment

No dosage adjustment necessary.

Dosage Forms

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Implant, Subcutaneous:

Zoladex: 3.6 mg (1 ea); 10.8 mg (1 ea)

Generic Equivalent Available (US)

No

Dosage Forms: Canada

Information with regard to form, strength, and availability of products uniquely available in Canada but currently not available in the US. Refer also to Dosage forms.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Implant, Subcutaneous:

Zoladex: 3.6 mg

Zoladex LA: 10.8 mg

Administration

SubQ: Administer implant by inserting needle at a 30 to 45 degree angle into the anterior abdominal wall below the navel line. Use caution while injecting goserelin into the anterior abdominal wall (due to the proximity of underlying inferior epigastric artery and its branches). Goserelin is an implant; therefore, do not attempt to eliminate air bubbles prior to injection (may displace implant). Do not attempt to

aspirate prior to injection; if a large vessel is penetrated, blood will be visualized in the syringe chamber (if vessel is penetrated, withdraw needle and inject elsewhere with a new syringe). Do not penetrate into muscle or peritoneum. Implant may be detected by ultrasound if removal is required. Monitor for signs/symptoms of abdominal hemorrhage. Use extra care when administering goserelin to patients with a low BMI and/or to patients receiving full dose anticoagulation (Canadian labeling does not recommend use in these patients due to the risk of vascular injury/bleeding).

Hazardous Drugs Handling Considerations

Hazardous agent (NIOSH 2016 [group 1]).

Use appropriate precautions for receiving, handling, administration, and disposal. Gloves (single) should be worn during receiving, unpacking, and placing in storage.

NIOSH recommends double gloving, a protective gown, ventilated engineering controls (a class II biological safety cabinet or a compounding aseptic containment isolator), and closed system transfer devices (CSTDs) for preparation. Double gloves and a protective gown are required during administration (NIOSH 2016).

Use

US labeling:

Breast cancer, advanced (3.6 mg only): Palliative treatment of advanced breast cancer in pre- and perimenopausal women (estrogen and progesterone receptor values may help to predict if goserelin is likely to be beneficial).

Endometrial thinning (3.6 mg only): Endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

Endometriosis (3.6 mg only): Management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy (goserelin experience for endometriosis has been limited to women 18 years and older treated for 6 months).

Prostate cancer, advanced (3.6 mg or 10.8 mg): Palliative treatment of advanced carcinoma of the prostate.

Prostate cancer, stage B2 to C (3.6 mg or 10.8 mg):: Management of locally confined stage T2b to T4 (stage B2 to C) prostate cancer (in combination with an antiandrogen [eg, flutamide]); begin goserelin and antiandrogen therapy 8 weeks prior to initiating radiation therapy and continue during radiation therapy.

Canadian labeling:

Breast cancer, advanced (3.6 mg only): Palliative treatment of advanced breast cancer in pre- and perimenopausal women (with estrogen and/or progesterone receptor-positive tumors).

Breast cancer, early (3.6 mg only): Alternative to standard adjuvant chemotherapy in pre- and perimenopausal women with early breast cancer (with estrogen and/or progesterone receptor-positive tumors) who are unsuitable for, intolerant to, or decline chemotherapy.

Endometrial thinning (3.6 mg only): Endometrial-thinning agent prior to endometrial ablation.

Endometriosis (3.6 mg or 10.8 mg): Hormonal management of endometriosis, including pain relief and reduction of endometriotic lesions (goserelin experience for endometriosis has been limited to women 18 years and older treated for 6 months).

Prostate cancer, advanced (3.6 mg or 10.8 mg): Palliative treatment of hormone-dependent advanced carcinoma of the prostate (stage M1 or D2).

Prostate cancer, locally advanced (3.6 mg or 10.8 mg): Management of locally advanced (T3 or T4) or bulky stage T2b to T2c prostate cancer (in combination with a nonsteroidal antiandrogen and radiation therapy); begin goserelin and antiandrogen therapy 8 weeks prior to initiating radiation therapy and continue until completion of radiation therapy.

Prostate cancer, locally advanced (3.6 mg or 10.8 mg): Adjuvant hormone therapy to external beam irradiation in locally advanced prostate cancer (stage T3 to T4).

Use: Off-Label

Breast cancer, advanced (second-line endocrine-based combination therapy); Prevention of early menopause during chemotherapy for early stage hormone receptor negative breast cancer

Adverse Reactions

Some frequencies not defined. Percentages reported with the 1-month implant:

>10%:

Cardiovascular: Vasodilatation (females 57%), peripheral edema (females 21%)

Central nervous system: Headache (females 32% to 75%; males 1% to 5%), emotional lability (females 60%), depression (females 54%; males 1% to 5%), pain (8% to 17%), dyspareunia (females 14%), insomnia (5% to 11%)

Dermatologic: Diaphoresis (females 16% to 45%; males 6%), acne vulgaris (females 42%; usually within 1 month after starting treatment), seborrhea (females 26%)

Endocrine & metabolic: Hot flash (females 57% to 96%; males 64%), decreased libido (females 48% to 61%), increased libido (females 12%)

Gastrointestinal: Abdominal pain (females 7% to 11%), nausea (5% to 11%)

Genitourinary: Vaginitis (75%), breast atrophy (females 33%), sexual disorder (males 21%), breast hypertrophy (females 18%), decrease in erectile frequency (18%), pelvic symptoms (females 18%), genitourinary signs and symptoms (lower; males 13%)

Hematologic & oncologic: Tumor flare (females 23%; males: Incidence not reported)

Infection: Infection (females 13%; males: Incidence not reported)

Neuromuscular & skeletal: Decreased bone mineral density (females 23%; ~4% decrease from baseline in 6 months; male: Incidence not reported), weakness (females 11%)

1% to 10%:

Cardiovascular: Edema (females 5%; male 7%), hypertension (1% to 6%), cardiac failure (males

5%), cardiac arrhythmia (males >1% to <5%), cerebrovascular accident (males >1% to <5%), peripheral vascular disease (males >1% to <5%), varicose veins (males >1% to <5%), chest pain (1% to <5%), myocardial infarction (males <1% to <5%), palpitations, tachycardia (females)

Central nervous system: Lethargy (females ≤8%), migraine (females 1% to 7%), dizziness (females 6%; male 5%), malaise (females ≤5%), chills (males >1% to <5%), anxiety (1% to <5%), nervousness (females 3% to 5%), voice disorder (females 3%), abnormality in thinking, drowsiness, paresthesia

Dermatologic: Skin rash (males 6% to 8%; female frequency not reported), hair disease (females 4%), pruritus (females 2%), alopecia, skin discoloration, xeroderma

Endocrine & metabolic: Gynecomastia (males 8%), hirsutism (7%), gout (males >1% to <5%), hyperglycemia (males >1% to <5%), weight gain (>1% to <5%)

Gastrointestinal: Anorexia (1% to 5%), gastric ulcer (males >1% to <5%), constipation (1% to <5%), diarrhea (1% to <5%), vomiting (1% to <5%), increased appetite (females 2%), dyspepsia, flatulence, xerostomia

Genitourinary: Pelvic pain (females 9%; males 6%), mastalgia (>1% to 7%), uterine hemorrhage (6%), vulvovaginitis (5%), breast swelling (males >1% to <5%), urinary tract obstruction (males: >1% to <5%), urinary tract infection (1% to <5%), urinary frequency, vaginal hemorrhage

Hematologic & oncologic: Anemia (males >1% to <5%), bruise, hemorrhage

Hypersensitivity: Hypersensitivity reaction

Infection: Sepsis (males >1% to <5%)

Local: Application site reaction (females 6%)

Neuromuscular & skeletal: Myalgia (females 3%, males frequency not reported), leg cramps (females 2%, males frequency not reported), hypertonia (females 1%; male frequency not reported), arthralgia, arthropathy

Ophthalmic: Amblyopia, dry eye syndrome

Renal: Renal insufficiency (<1% to >5%)

Respiratory: Upper respiratory tract infection (males 7%), chronic obstructive pulmonary disease (males 5%), flu-like symptoms (females 5%, male frequency not reported), pharyngitis (females 5%), sinusitis (females ≥1%; male frequency not reported), bronchitis, cough, epistaxis, rhinitis

Miscellaneous: Fever

<1%, postmarketing, and/or case reports (with monthly or 3-month implant): Anaphylaxis, bone fracture, convulsions, decreased glucose tolerance, decreased HDL cholesterol, deep vein thrombosis, diabetes mellitus, hypercalcemia, hypercholesterolemia, hyperlipidemia, hypotension, increased HDL cholesterol, increased LDL cholesterol, increased serum ALT, increased serum AST, increased serum triglycerides, injection site reaction (including vascular injury, pain, hematoma, hemorrhage, hemorrhagic shock), osteoporosis, ovarian cyst, ovarian hyperstimulation syndrome, pituitary apoplexy, pituitary neoplasm (including adenoma), pulmonary embolism, psychotic reaction, transient ischemic attacks

Contraindications

US labeling: Hypersensitivity to goserelin, GnRH, GnRH agonist analogues, or any component of the formulation; pregnancy (except if using for palliative treatment of advanced breast cancer)

Canadian labeling: Hypersensitivity to goserelin or any component of the formulation; undiagnosed vaginal bleeding

Warnings/Precautions

Concerns related to adverse effects:

• Cervical resistance: Cervical resistance may be increased; use caution when dilating the cervix for endometrial ablation.

• Decreased bone density: Has been reported in women and may be irreversible; use caution if other risk factors are present; evaluate and institute preventive treatment if necessary.

• Hypercalcemia: Hypercalcemia has been reported in prostate and breast cancer patients with bone metastases. Initiate appropriate management if hypercalcemia occurs.

• Hyperglycemia: Hyperglycemia has been reported in males and may manifest as diabetes or worsening of preexisting diabetes (worsening glycemic control). Monitor blood glucose and HbA_{1c} and manage diabetes appropriately.

• Hypersensitivity: Hypersensitivity reactions (including acute anaphylactic reactions) and antibody formation may occur; monitor.

• Injection site injury: Injection site and vascular injury, including pain, hematoma, hemorrhage and hemorrhagic shock (requiring blood transfusions or surgical intervention) have been reported with goserelin. Use extra caution when administering to patients with a low BMI and/or to patients receiving full dose anticoagulation (Canadian labeling does not recommend use of goserelin in these patients due to the risk of vascular injury/bleeding). Use caution while injecting goserelin into the anterior abdominal wall (due to the proximity of underlying inferior epigastric artery and its branches). Monitor for signs/symptoms of abdominal hemorrhage. Inform patient to immediately report abdominal pain, abdominal distention, dyspnea, dizziness, hypotension, and/or altered level of consciousness.

• Pituitary apoplexy: Rare cases of pituitary apoplexy (frequently secondary to pituitary adenoma) have been observed with GnRH agonist administration (onset from 1 hour to usually <2 weeks); may present as sudden headache, vomiting, visual or mental status changes, and infrequently cardiovascular collapse; immediate medical attention required.

• Tumor flare: Transient increases in serum testosterone (in men with prostate cancer) and estrogen (in women with breast cancer) may result in a worsening of disease signs and symptoms (tumor flare) during the first few weeks of treatment. Some patients experienced a temporary worsening of bone pain, which may be managed symptomatically. Spinal cord compression and urinary tract obstruction have been reported when used for prostate cancer; closely observe patients for symptoms (eg, ureteral obstruction, weakness, paresthesias) in first few weeks of therapy. Manage with standard treatment; consider orchiectomy for extreme cases.

Disease-related concerns:

• Cardiovascular disease: Androgen deprivation therapy may increase the risk for cardiovascular disease (Levine, 2010). An increased risk for MI, sudden cardiac death, and stroke has been observed. Monitor for signs/symptoms of cardiovascular disease; manage according to current clinical practice. Androgen deprivation therapy may cause prolongation of the QT/QTc interval; evaluate risk versus benefit in patients with congenital long QT syndrome, heart failure, frequent electrolyte abnormalities, and in patients taking medication known to prolong the QT interval. Correct electrolytes prior to initiation and consider periodic electrolyte and ECG monitoring.

Concurrent drug therapy issues:

• Drug-drug interactions: Potentially significant interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information.

Special populations:

• Obese patients: A decreased AUC may be observed when using the 3-month implant in obese patients. Monitor testosterone levels if desired clinical response is not observed.

• Underweight patients: Use extra care when administering to patients with a low BMI.

• Women: Women of childbearing potential should not receive therapy until pregnancy has been excluded. Nonhormonal contraception is recommended during therapy and for 12 weeks after therapy is discontinued. Chronic administration may result in effects on reproductive function due to antigonadotropic properties.

Dosage form specific issues:

• Implant removal: If removal is necessary, implant may be located by ultrasound.

Metabolism/Transport Effects

None known.

Drug Interactions

(For additional information: Launch drug interactions program) Lexicomp®

Antidiabetic Agents: Hyperglycemia-Associated Agents may diminish the therapeutic effect of Antidiabetic Agents. *Risk C: Monitor therapy*

Choline C 11: Luteinizing Hormone-Releasing Hormone Analogs may diminish the therapeutic effect of Choline C 11. *Risk C: Monitor therapy*

Corifollitropin Alfa: Luteinizing Hormone-Releasing Hormone Analogs may enhance the therapeutic effect of Corifollitropin Alfa. *Risk X: Avoid combination*

Highest Risk QTc-Prolonging Agents: Moderate Risk QTc-Prolonging Agents may enhance the QTc-prolonging effect of Highest Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

Hydroxychloroquine: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

Indium 111 Capromab Pendetide: Luteinizing Hormone-Releasing Hormone Analogs may diminish the diagnostic effect of Indium 111 Capromab Pendetide. *Risk X: Avoid combination*

Ivabradine: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

MiFEPRIStone: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

Moderate Risk QTc-Prolonging Agents: May enhance the QTc-prolonging effect of other Moderate Risk QTc-Prolonging Agents. Management: Avoid such combinations when possible. Use should be accompanied by close monitoring for evidence of QT prolongation or other alterations of cardiac rhythm. *Risk D: Consider therapy modification*

Probucol: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

Promazine: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

QTc-Prolonging Agents (Indeterminate Risk and Risk Modifying): May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk C: Monitor therapy*

Vinflunine: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk X: Avoid combination*

Xipamide: May enhance the QTc-prolonging effect of Moderate Risk QTc-Prolonging Agents. *Risk C: Monitor therapy*

Pregnancy Risk Factor X (endometriosis, endometrial thinning); D (advanced breast cancer) (show table)

Pregnancy Implications Adverse events were observed in animal reproduction studies. Goserelin induces hormonal changes which increase the risk for fetal loss and use is contraindicated in pregnancy unless being used for palliative treatment of advanced breast cancer.

Breast cancer: If used for the palliative treatment of breast cancer during pregnancy, the potential for increased fetal loss should be discussed with the patient.

Endometriosis, endometrial thinning: Use is contraindicated during pregnancy. Women of childbearing potential should not receive therapy until pregnancy has been excluded. Nonhormonal contraception is recommended for premenopausal women during therapy and for 12 weeks after therapy is discontinued. Although ovulation is usually inhibited and menstruation may stop, pregnancy prevention is not ensured during goserelin therapy. Changes in reproductive function may occur following chronic administration.

Breast-Feeding Considerations It is not known if goserelin is excreted in breast milk, although goserelin is inactivated when used orally. Due to the potential for serious adverse reactions in the breast-feeding infant, a decision should be made to discontinue breast-feeding or to discontinue the drug, taking into account the importance of treatment to the mother.

Monitoring Parameters Monitor blood glucose and HbA_{1c} (periodically), bone mineral density, serum calcium, cholesterol/lipids; monitor for signs/symptoms of abdominal hemorrhage following injection.

Prostate cancer: Consider periodic ECG and electrolyte monitoring. Monitor for weakness, paresthesias, tumor flare, urinary tract obstruction, and spinal cord compression in first few weeks of therapy.

Mechanism of Action Goserelin (a gonadotropin-releasing hormone [GnRH] analog) causes an initial increase in luteinizing hormone (LH) and follicle stimulating hormone (FSH), chronic administration of goserelin results in a sustained suppression of pituitary gonadotropins. Serum testosterone falls to levels comparable to surgical castration. The exact mechanism of this effect is unknown, but may be related to changes in the control of LH or down-regulation of LH receptors.

Pharmacodynamics/Kinetics

Onset:

Females: Estradiol suppression reaches postmenopausal levels within 3 weeks and FSH and LH are suppressed to follicular phase levels within 4 weeks of initiation

Males: Testosterone suppression reaches castrate levels within 2 to 4 weeks after initiation

Duration:

Females: Estradiol, LH and FSH generally return to baseline levels within 12 weeks following the last monthly implant.

Males: Testosterone levels maintained at castrate levels throughout the duration of therapy.

Absorption: SubQ: Rapid and can be detected in serum in 30 to 60 minutes; 3.6 mg: released slowly in first 8 days, then rapid and continuous release for 28 days

Distribution: V_d: Male: 44.1 L; Female: 20.3 L

Protein binding: ~27%

Metabolism: Hepatic hydrolysis of the C-terminal amino acids

Time to peak, serum: SubQ: Male: 12 to 15 days, Female: 8 to 22 days

Excretion: Urine (>90%; 20% as unchanged drug)

Pricing: US

Implant (Zoladex Subcutaneous)

3.6 mg (1): $660.60

10.8 mg (1): $1981.79

Disclaimer: The pricing data provide a representative AWP and/or AAWP price from a single manufacturer of the brand and/or generic product, respectively. The pricing data should be used for benchmarking purposes only, and as such should not be used to set or adjudicate any prices for reimbursement or purchasing functions. Pricing data is updated monthly.

International Brand Names Zoladex (AE, AR, AT, BB, BD, BE, BF, BG, BJ, BM, BR, BS, BZ, CH, CI, CL, CN, CR, CU, CY, CZ, DE, DK, DO, EC, EE, EG, ES, ET, FI, FR, GB, GH, GM, GN, GR, GT, GY, HK,

HN, HR, HU, ID, IE, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KR, KW, LK, LR, LT, LU, LV, LY, MA, ML, MR, MT, MU, MW, MY, NE, NG, NI, NL, NO, OM, PA, PE, PH, PK, PL, PR, PT, RO, RU, SC, SD, SE, SG, SK, SL, SN, SR, SV, SY, TH, TN, TR, TT, TW, TZ, UA, UG, UY, VE, VN, YE, ZA, ZM, ZW); Zoladex Depot (AE, BH, KR, LB, QA, SA); Zoladex Implant (AT, AU, BE, BG, CH, CZ, DE, DK, EE, FI, FR, GB, GR, HN, IE, IT, NO, PL, PT, RU, SE, SK, TR); Zoladex Inj. (NZ); Zoladex LA (AR, BB, BH, BM, BS, CO, CU, EC, HR, ID, IL, IN, JM, LB, LK, LU, LV, MT, MY, NL, PH, PR, QA, RO, SG, TH, TT, TW, UY); Zpladex (SI)

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