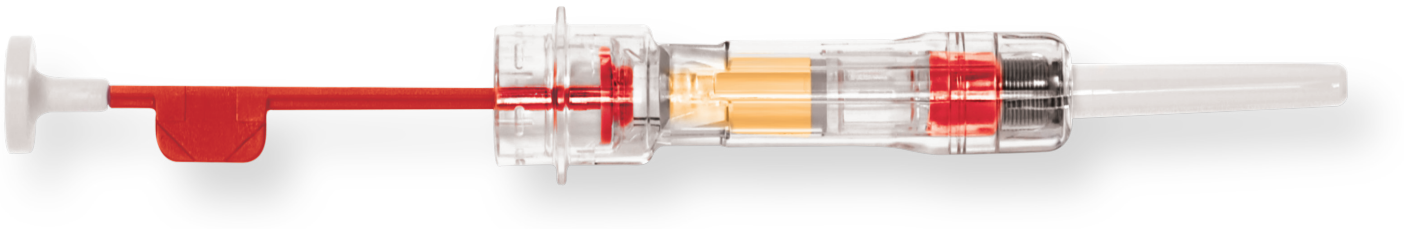
Zoladex®
(goserelin implant)

A Simple Guide to Administration

Convenient ready-to-use, biodegradable GnRH agonist implant[1,2]

GnRH=gonadotropin-releasing hormone.



ZOLADEX 3.6 mg syringe –
For illustration only.

INDICATIONS

ZOLADEX (goserelin implant) is a Gonadotropin Releasing Hormone (GnRH) agonist.

ZOLADEX 3.6 mg and ZOLADEX 10.8 mg are indicated for:

- Use in combination with flutamide for the management of locally confined carcinoma of the prostate
- Palliative treatment of advanced carcinoma of the prostate

ZOLADEX 3.6 mg is indicated for:

- The management of endometriosis
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women

SELECT SAFETY INFORMATION

Systemic hypersensitivity, antibody formation, and acute anaphylactic reactions have been reported in patients receiving ZOLADEX. ZOLADEX is contraindicated in patients with known hypersensitivity to GnRH, GnRH agonist, or any of the components in ZOLADEX.

Please see additional Important Safety Information enclosed.
Please see accompanying Full Prescribing Information for ZOLADEX 3.6 mg and ZOLADEX 10.8 mg.

ZOLADEX SafeSystem® Syringe: Convenient ready-to-use GnRH agonist[1,2]

Designed for safe and efficient administration[1,2]

ZOLADEX features:

- A sterile, siliconized, triple-beveled hypodermic needle with easy-glide SafeSystem® Syringe
- No assembly, mixing, or refrigeration required
- Implant provides consistent, reliable delivery of medication
- Each syringe is provided with a convenience pack (contains gauze, alcohol wipe, and bandage)
- Designed with a protective needle sleeve to reduce needlestick injuries[3]
  - SafeSystem® Syringe is designed to automatically cover the needle upon withdrawal

Convenience pack

ZOLADEX 10.8 mg syringe and convenience pack – For illustration only.

Zoladex®
(goserelin implant)

1.70 min

In a study with nurses,
it took an average of 1.70 minutes
to prepare and deliver ZOLADEX 3.6 mg[4]

91% agreed that it was **easy to prepare** ZOLADEX prior to administration[4]

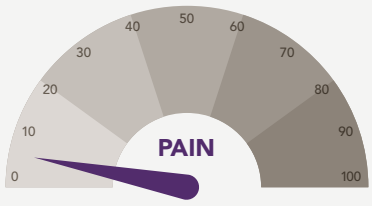
85% agreed that there were **good safety precautions** with ZOLADEX[4]

76% agreed that the ZOLADEX syringe was **easy to manipulate[4]**

67% felt confident about using the ZOLADEX syringe[4]

Randomized crossover study with 82 nurses timed in the administration (preparation and delivery) of the system used to administer ZOLADEX and the system used to administer another GnRH agonist.* Preferences and perceptions of the ease of use and relative safety of the two injection systems were also assessed via questionnaire.[4]

The majority of patients reported minimal pain (VAS <10 mm) from the ZOLADEX 3.6 mg injection[5]



Injection 1: Median range 5 (0-38) mm.
Injection 2: Median range 7 (0-51) mm.

VAS=visual analogue scale.

In a study with patients, there was **no significant difference between the pain levels experienced** from injections of ZOLADEX compared to another subcutaneous GnRH agonist.[5]

A total of 50 patients were blindfolded and administered either ZOLADEX or another GnRH agonist* into the anterior abdominal wall. Each group (24 ZOLADEX and 26 other GnRH agonist) received 2 injections 4 weeks apart. Following each injection, patients were asked to record the pain of injection on a visual analogue scale ranging from 0 mm (no discomfort) to 100 mm (maximal discomfort).[5]

*GnRH agonist used for comparison was a product marketed only in the UK.

SELECT SAFETY INFORMATION

Injection site injury and vascular injury have been reported with ZOLADEX. Extra care should be taken when administering ZOLADEX to patients with low BMI and/or to patients receiving full dose anticoagulation.

Tumor Flare Phenomenon: Transient worsening of tumor symptoms may occur in the first few weeks of therapy in patients being treated for cancer. Monitor patients at risk for complications of tumor flare including ureteral obstruction, spinal cord compression, and increased bone pain.

Please see additional Important Safety Information enclosed.
Please see accompanying Full Prescribing Information for ZOLADEX 3.6 mg and ZOLADEX 10.8 mg.

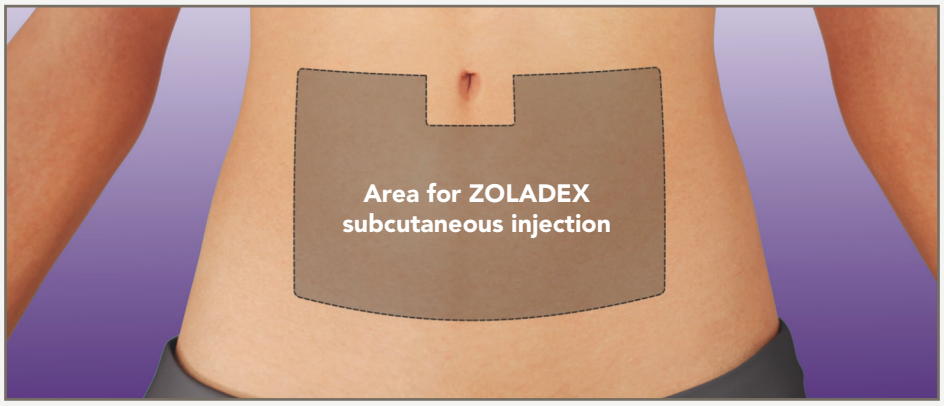
ZOLADEX administration technique

ZOLADEX SafeSystem® Syringe: Convenient ready-to-use GnRH agonist[1,2] No assembly, mixing, or refrigeration required—the siliconized hypodermic needle with easy-glide SafeSystem® Syringe comes ready to administer.

1 Prepare the patient:

Put the patient in a comfortable position with the upper part of the body slightly raised. Prepare an area of the anterior abdominal wall below and two inches out from the navel line with an alcohol swab.

NOTE: Caution should be taken when injecting into the anterior abdominal wall due to the proximity of underlying inferior epigastric artery and its branches.



2 Prepare the injection:

Examine the foil pouch for damage, then open. Empty the pouch onto a clean surface rather than pulling the syringe out of the pouch, as it is possible to inadvertently pull the plunger off of the syringe.

Hold the syringe at a slight angle to the light and confirm at least part of the ZOLADEX implant is visible. There is no need to remove air bubbles, like with liquid injections, and partially depressing the plunger prior to administration may cause the implant to fall from the syringe.

Gently peel the plastic safety tab up and away from the plunger and discard it. Remove the needle cover.

NOTE: If too much force is used when removing the plastic safety tab, the plunger can be pulled off.

3 Complete the injection:

Pinch the patient's skin using aseptic technique at the prepared injection site. With the bevel of the needle facing up, grasp the protective sleeve of the syringe with the pointer finger, middle finger, and thumb. If this finger placement is not comfortable, adjust so you have control of the device.

Insert the needle subcutaneously at a 30- to 45-degree angle to the skin in one continuous, deliberate motion until the protective sleeve touches the skin.

NOTE: The ZOLADEX syringe cannot be used for aspiration. If the hypodermic needle penetrates a large vessel, blood will be seen instantly in the syringe chamber. If a vessel is penetrated, withdraw the needle and inject with a new syringe elsewhere. Monitor patients for signs or symptoms of abdominal hemorrhage.

Use extra care when administering ZOLADEX to patients with low BMI and/or patients receiving full dose anticoagulation.

While continuing to pinch the patient's abdomen, move your fingers back to the syringe finger grip and place your thumb on the plunger. Grasping the syringe below the finger grip on the protective sleeve may prevent the protective sleeve from activating.

While grasping the finger grip, depress the plunger until you cannot depress it any further. Use sufficient force to depress the plunger, as a degree of resistance can be experienced.

After fully depressing the plunger, begin withdrawing the needle, and the SafeSystem® Syringe protective sleeve will deploy to cover the syringe. The needle itself does not retract. Dispose of the syringe in an approved sharps collector.

View a step-by-step administration video at **ZOLADEXhcp.com**

IMPORTANT SAFETY INFORMATION

GENERAL

Systemic hypersensitivity, antibody formation, and acute anaphylactic reactions have been reported in patients receiving ZOLADEX. ZOLADEX is contraindicated in patients with known hypersensitivity to GnRH, GnRH agonist, or any of the components in ZOLADEX.

Tumor Flare Phenomenon: Transient worsening of tumor symptoms may occur in the first few weeks of therapy in patients being treated for cancer. Monitor patients at risk for complications of tumor flare including ureteral obstruction, spinal cord compression, and increased bone pain.

Hypercalcemia has been reported in patients with bone metastases treated with ZOLADEX. Monitor and manage appropriately.

Injection site injury and vascular injury have been reported with ZOLADEX. Extra care should be taken when administering ZOLADEX to patients with low BMI and/or to patients receiving full dose anticoagulation.

FEMALES

ZOLADEX is contraindicated during pregnancy unless used for palliative treatment of advanced breast cancer. If used during pregnancy, the patient should be advised of the potential hazard to the fetus. Otherwise, pregnancy must be excluded and effective nonhormonal contraception must be used by all premenopausal women during ZOLADEX therapy and for 12 weeks following discontinuation of therapy.

ZOLADEX may cause an increase in cervical resistance. Therefore, caution is recommended when dilating the cervix for endometrial ablation.

Depression may occur or worsen in women receiving GnRH agonists, including ZOLADEX. Monitor and manage appropriately.

MALES

Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Monitor blood glucose levels and manage according to current clinical practice.

Increased risk of myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. Patients should be monitored for cardiovascular disease and be managed according to current clinical practice.

Androgen deprivation therapy may prolong the QT interval. Consider risks and benefits.

ADVERSE REACTIONS

In men, the most common adverse reactions (>10%) include hot flashes, sexual dysfunction, decreased erections and lower urinary tract symptoms.

In women, the most common adverse reactions (>20%) include hot flashes, vaginitis, headache, emotional lability, decreased libido, sweating, depression, acne, breast atrophy, seborrhea, and peripheral edema.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

Please see accompanying Full Prescribing Information for ZOLADEX 3.6 mg and ZOLADEX 10.8 mg.

INDICATIONS

ZOLADEX (goserelin implant) is a Gonadotropin Releasing Hormone (GnRH) agonist.

ZOLADEX 3.6 mg and ZOLADEX 10.8 mg are indicated for:

- Use in combination with flutamide for the management of locally confined carcinoma of the prostate
- Palliative treatment of advanced carcinoma of the prostate

ZOLADEX 3.6 mg is indicated for:

- The management of endometriosis
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women

References: 1. ZOLADEX® (goserelin implant). Prescribing Information. TerSera Therapeutics LLC. **2.** ZOLADEX® injection education support. https://www.zoladexhcp.com/dosing-administration/. Accessed November 15, 2023. **3.** Moser MA. Engineering out needle stick injuries (safety devices). *The Safe Angle*. Summer 2004;5-7. **4.** Morgan G, Cooley C. Injection systems for two luteinising hormone-releasing hormone agonists: a comparative assessment of administration times and nurses' perceptions. *Eur J Oncol Nurs*. 2005;9(4):334-340. **5.** Montgomery BS, Borwell JP, Higgins DM. Does needle size matter? Patient experience of luteinising hormone-releasing hormone analogue injection. *Prostate Cancer Prostatic Dis*. 2005;8(1):66-68.

ZOLADEX Administration Guide

To request in-office injection training with a Clinical Nurse Educator or Account Manager, please visit

ZOLADEXhcp.com/request-a-rep

Urgent questions about ZOLADEX administration?

The **TerSera Nurse On-Demand** program provides nurse-to-nurse, real-time education

Call 1-877-99-NURSE (68773)
Monday-Friday, 8 AM to 5:30 PM ET
Messages left after hours will be returned the next business day.

TerSera SupportSource

Additional support services, including reimbursement information, patient support, and co-pay card information are available at:

ZOLADEXhcp.com
1-844-ZOLADEX
(1-844-965-2339)

TerSera® therapeutics

ZOL-P-1068 v6 (05/2025)

Zoladex® (goserelin implant)