

# Only **Zoladex**<sup>®</sup> goserelin acetate implant

The only ready-to-use, biodegradable  
GnRH\* agonist implant<sup>1,2</sup>



A SIMPLE GUIDE TO ADMINISTRATION

\*GnRH: gonadotropin-releasing hormone.

# Zoladex SafeSystem<sup>®</sup>: The only ready-to-use GnRH agonist<sup>1,2</sup>

Zoladex meets the needs of nurses<sup>4,5</sup>

Designed to provide consistent, reliable delivery of Zoladex<sup>1,2</sup>

### Zoladex features:

- A sterile, siliconized, triple-beveled hypodermic needle with easy-glide SafeSystem
- 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 and guard to reduce needlestick injuries<sup>3</sup>
  - Zoladex SafeSystem needle is automatically covered upon withdrawal

### Actual sizes:



## 1.70 min

In a study with nurses, it took an average of 1.70 minutes **to prepare and deliver Zoladex<sup>4</sup>**

**91%**

agreed that it was **easy to prepare** Zoladex prior to administration<sup>4</sup>

**85%**

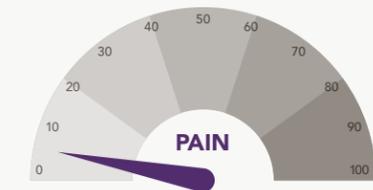
agreed that there were **good safety precautions** with Zoladex<sup>4</sup>

**76%**

agreed that the Zoladex syringe was **easy to manipulate<sup>4</sup>**

Randomized crossover study with 82 nurses timed in the administration (preparation and delivery) of the system used to administer Zoladex and the vial system used to administer leuprolide acetate. Preferences and perceptions of the ease of use and relative safety of the two injection systems were also assessed.<sup>4</sup>

The majority of patients reported minimal pain (VAS\* <10 mm) from the Zoladex injection<sup>5</sup>



In a study with patients, there was **no significant difference between the pain levels experienced** from injections of Zoladex compared to injections of intramuscular leuprolide acetate<sup>5</sup>

A total of 50 patients were blindfolded and administered either Zoladex or leuprolide acetate into the anterior abdominal wall. Each group (24 Zoladex and 26 leuprolide acetate) 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).<sup>5</sup>

**Zoladex<sup>®</sup>**  
goserelin acetate implant

# A visual comparison of selected GnRH agonist delivery systems

**Zoladex**<sup>®</sup>  
goserelin acetate implant

## ZOLADEX SAFESYSTEM<sup>®</sup>

Actual sizes:

3.6 mg:  
1 cm in length

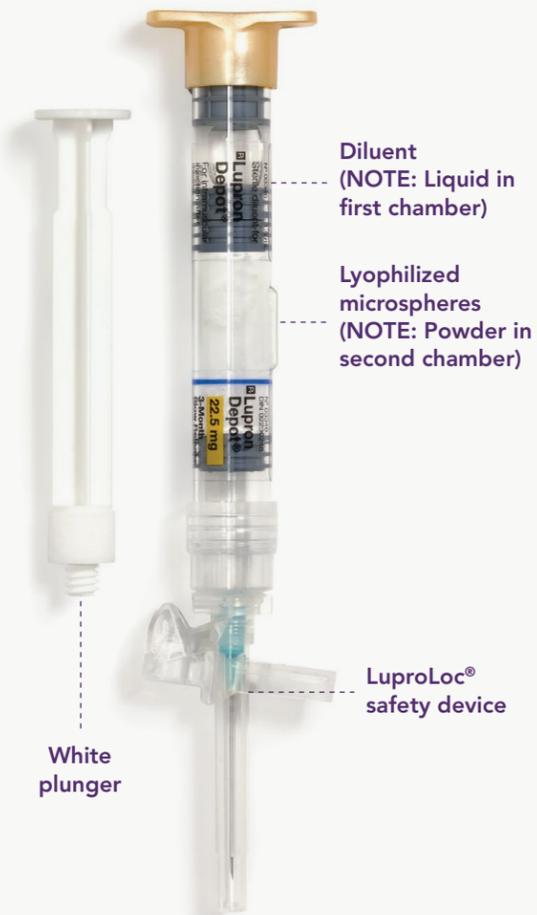


10.8 mg:  
1.7 cm in length

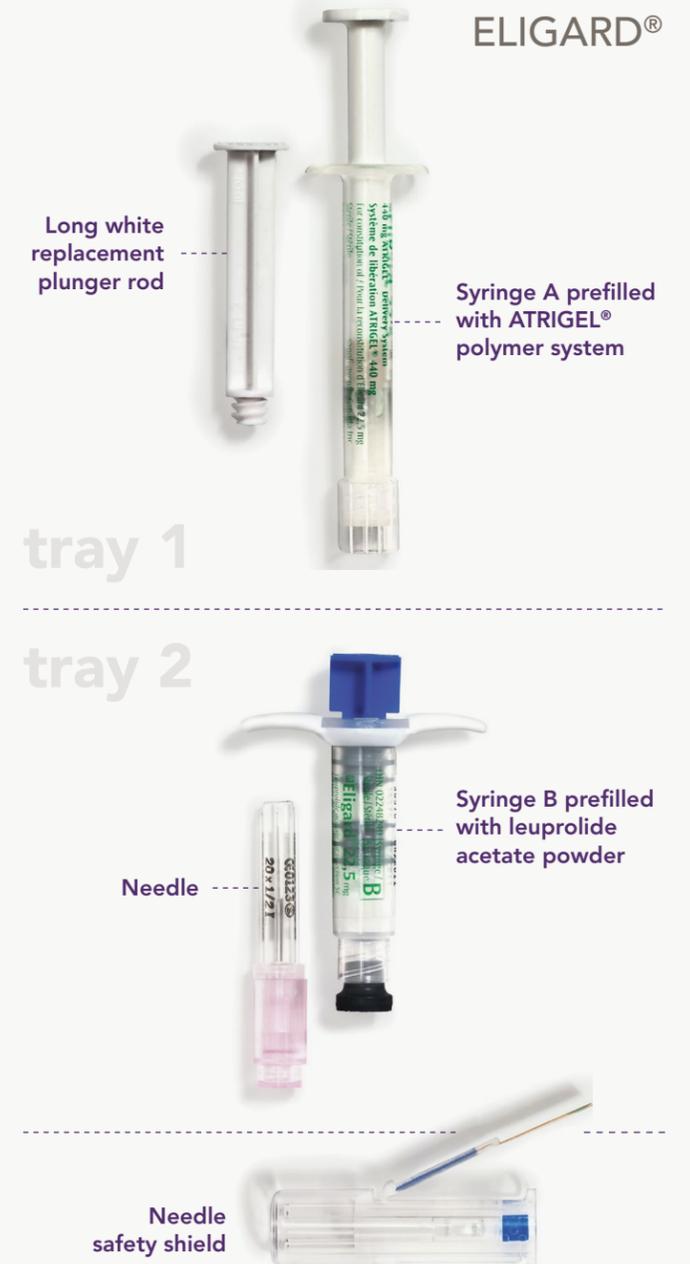


## LUPRON DEPOT<sup>®</sup>

Prefilled dual-chamber syringe



## ELIGARD<sup>®</sup>



# Important Safety Information About ZOLADEX<sup>®</sup> (goserelin acetate implant)

**Zoladex**<sup>®</sup>  
goserelin acetate implant

Anaphylactic reactions to ZOLADEX have been reported in the medical literature. ZOLADEX is contraindicated in patients with a known hypersensitivity to GnRH, GnRH agonist analogues, or any of the components in ZOLADEX.

ZOLADEX is contraindicated during pregnancy unless used for palliative treatment of advanced breast cancer. ZOLADEX can cause fetal harm when administered to a pregnant woman. If used during pregnancy, the patient should be apprised of the potential hazard to the fetus. There is an increased risk for pregnancy loss due to expected hormonal changes that occur with ZOLADEX treatment. ZOLADEX should not be given to women with undiagnosed abnormal vaginal bleeding.

Pregnancy must be excluded for use in benign gynecological conditions. Women should be advised against becoming pregnant while taking ZOLADEX. Effective nonhormonal contraception must be used by all premenopausal women during ZOLADEX therapy and for 12 weeks following discontinuation of therapy.

Transient worsening of tumor symptoms, or the occurrence of additional signs and symptoms of breast cancer, may occasionally develop during the first few weeks of treatment. Some patients may experience a temporary increase in bone pain. Monitor patients at risk for complications of tumor flare.

Hyperglycemia and an increased risk of developing diabetes or worsening of glycemic control in patients with diabetes have been reported in men receiving GnRH agonists like ZOLADEX. Monitor blood glucose levels and glycosylated hemoglobin (HbA1c) periodically and manage according to current clinical practice.

Increased risk of developing myocardial infarction, sudden cardiac death, and stroke has been reported in association with use of GnRH agonists like ZOLADEX in men. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of

development of cardiovascular disease and be managed according to current clinical practice.

Hypercalcemia has been reported in some prostate and breast cancer patients with bone metastases after starting treatment with ZOLADEX. If hypercalcemia does occur, appropriate treatment measures should be initiated.

Hypersensitivity, antibody formation, and acute anaphylactic reactions have been reported with GnRH agonist analogues.

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

Androgen deprivation therapy may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Injection site injury and vascular injury including pain, hematoma, hemorrhage, and hemorrhagic shock, requiring blood transfusions and surgical intervention, 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.

Treatment with ZOLADEX may be associated with a reduction in bone mineral density over the course of treatment. Data suggest a possibility of partial reversibility. In women, current available data suggest that recovery of bone loss occurs on cessation of therapy in the majority of patients.

In women the most frequently reported adverse reactions were related to hypoestrogenism. The

adverse reaction profile was similar for women treated for breast cancer, dysfunctional uterine bleeding, and endometriosis.

The most commonly reported adverse reactions with ZOLADEX in clinical trials for endometriosis were hot flashes (96%), vaginitis (75%), headache (75%), decreased libido (61%), emotional lability (60%), depression (54%), sweating (45%), acne (42%), breast atrophy (33%), seborrhea (26%), and peripheral edema (21%).

The most commonly reported adverse reactions with ZOLADEX in clinical trials for endometrial thinning were vasodilation/hot flashes (57%), headache (32%), sweating (16%), and abdominal pain (11%).

The most commonly reported adverse reactions with ZOLADEX in breast cancer clinical trials were hot flashes (70%), decreased libido (47.7%), tumor flare (23%), nausea (11%), edema (5%), and malaise/fatigue/lethargy (5%). Injection site reactions were reported in less than 1% of patients.

The most commonly observed adverse reactions during ZOLADEX treatment for prostatic carcinoma were due to the expected physiological effects from decreased testosterone levels. The most common adverse reactions (incidence of >5% in prostate clinical trials) were:

- For ZOLADEX 3.6-mg: Hot flashes (62%), sexual dysfunction (21%), decreased erections (18%), lower urinary tract symptoms (13%), lethargy (8%), pain (worsened in the first 30 days) (8%), edema (7%), upper respiratory infection (7%), rash (6%), and sweating (6%).
- For ZOLADEX 10.8-mg: Hot flashes (64%), pain (general) (14%), gynecomastia (8%), pelvic pain (6%), and bone pain (6%).

In the locally advanced carcinoma of the prostate clinical trial, additional adverse event data were collected for the combination therapy with radiation group during both the hormonal treatment and

hormonal treatment plus radiation phases of this study. Adverse experiences (incidence >5%) in both phases of this study were hot flashes (46%), diarrhea (40%), nausea (9%), and skin rash (8%). Treatment with ZOLADEX and flutamide did not add substantially to the toxicity of radiation treatment alone.

## Indications

Management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate in combination with flutamide. Treatment with ZOLADEX and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.

Palliative treatment of advanced carcinoma of the prostate.

Management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with ZOLADEX for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.

Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

Palliative treatment of advanced breast cancer in pre- and perimenopausal women.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

**Please see [www.Zoladexhcp.com](http://www.Zoladexhcp.com) or your local representative for the Full Prescribing Information.**

Individual patient results may vary.

**References:** 1. ZOLADEX<sup>®</sup> (goserelin acetate implant) 3.6 mg prescribing information, TerSera Therapeutics LLC. 2. ZOLADEX injection education support. <https://www.Zoladexhcp.com/injection-edu-support.html>. Accessed March 20, 2018. 3. Moser MA. Engineering out needle stick injuries (safety devices). *The Safe Angle Summer 2004*;5-7. 4. Morgan G and 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;9:334-340. 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;8:66-68.

# Zoladex administration guide

**PREPARATION: No refrigeration or premixing is required with Zoladex**—the siliconized hypodermic needle with easy-glide SafeSystem comes ready to administer.

## ADMINISTRATION



- 1** Clean an area of the anterior abdominal wall (below the navel) for injection using an alcohol swab.



- 2** Inspect the foil pouch and syringe for damage. Remove the syringe from the pouch and hold it at a slight angle to make sure part of the implant is visible. Remove the plastic safety tab and needle cover.



- 3** **Pinch the patient's skin** using aseptic technique at the prepared injection site, and hold the needle with the **bevel facing up** at an injection **angle of 30°-45°**.  
*NOTE: Extra care should be taken with patients with low BMI and/or patients receiving a full dose of anticoagulation.*



- 4** **Insert the needle**, with the bevel facing up, until the protective sleeve touches the patient's skin. Take care not to penetrate the muscle or peritoneum.  
*NOTE: If the needle penetrates a large blood vessel, blood will immediately be seen in the syringe chamber. If this occurs, withdraw the needle and inject a new syringe at a new location. Monitor patients for signs of abdominal hemorrhage.*



- 5** **Depress the plunger** until you hear a "**CLICK**." The click ensures the SafeSystem has been activated and the implant has been deposited in the correct location.



- 6** **Withdraw the needle** and allow the protective sleeve to slide and cover the needle; dispose in an approved sharps container.

View a step-by-step administration video at [www.Zoladexhcp.com](http://www.Zoladexhcp.com)

Additional support services such as reimbursement information, patient support, and in-office injection training are available by calling **1-844-ZOLADEX (1-844-965-2339)**.

For questions about Zoladex, please contact TerSera Therapeutics, from 8 AM to 6 PM EST, at 1-888-374-6627. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088. This product information is intended for US health care professionals only.



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