

## PATIENT MEDICATION INFORMATION FOR PROSTATE CANCER

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **ZOLADEX® LA** **Goserelin Implant**

Read this carefully before you start taking **ZOLADEX® LA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZOLADEX LA**.

#### **Serious Warnings and Precautions**

ZOLADEX LA should be prescribed and managed by a healthcare professional experienced with using this type of drug.

ZOLADEX LA should be administered by a healthcare professional experienced in administering deep subcutaneous injections.

ZOLADEX LA may cause:

- worsening of tumour symptoms at the beginning of treatment;
- bone thinning (osteoporosis);
- injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of ZOLADEX LA. In rare cases this has caused severe bleeding (with some cases requiring surgical treatment).

#### **What is ZOLADEX LA used for?**

In men, ZOLADEX LA is used to treat hormone-dependent prostate cancer that is advanced and/or has spread to other parts of body. It may be used alone or in combination with other treatments for prostate cancer called:

- non-steroidal anti-androgen and radiation treatment, or
- external beam irradiation.

#### **How does ZOLADEX LA work?**

ZOLADEX LA contains a medicine called goserelin. It belongs to a group of medicines called “Gonadotropin releasing hormone analogues”.

ZOLADEX LA works by reducing the amount of testosterone produced by your body.

#### **What are the ingredients in ZOLADEX LA?**

Medicinal ingredients: goserelin (as goserelin acetate)

Non-medicinal ingredients: Lactide-glycolide copolymer

#### **ZOLADEX LA comes in the following dosage forms:**

Implant: 10.8 mg

ZOLADEX LA comes in a hard, cream-coloured, rod-shaped implant.

#### **Do not use ZOLADEX LA if you:**

- are allergic to goserelin acetate or any of the ingredients in this medicine.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZOLADEX LA. Talk about any health conditions or problems you may have, including if you:**

- have or have had any problems passing urine
- have kidney problems
- have a family history of severe osteoporosis (a condition that affects the strength of your bones)
- have low bone mineral density
- take other medicines that cause thinning of the bones (such as corticosteroids or anti-seizure medicines)
- have a low red blood cell count (anemia)
- have heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using ZOLADEX LA.
- have diabetes
- are taking blood thinners
- have a low body mass index (less than 18.5). You may be at higher risk of injury to blood vessels when using ZOLADEX LA.

**Other warnings you should know about:**

- **Check-ups and testing**
  - You will have regular visits with your healthcare professional during treatment with ZOLADEX LA. They may:
    - do regular physical exams and lab tests
    - do blood tests to check your electrolyte, glucose and hormone levels
    - do an electrocardiogram (ECG) to check your heart health
    - check for signs of side effects
- **Children (under 18 years of age)**
  - You should not be given ZOLADEX LA if you are under 18 years of age.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

**The following may interact with ZOLADEX LA:**

- medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);
- medicines that might increase the risk of heart rhythm problems when used with some other drugs, such as:
  - methadone (used for pain relief),
  - moxifloxacin (an antibiotic), and
  - antipsychotics (used for serious mental illnesses).

**How to take ZOLADEX LA:**

- ZOLADEX LA is injected under the skin on your abdomen by a healthcare professional. It is important that you continue ZOLADEX LA treatment, even if you are feeling well. Your healthcare professional will decide when it is time for you to stop.

**Usual dose:**

One injection every 3 months (13 weeks)

## Overdose:

If you think you, or a person you are caring for, have taken too much ZOLADEX LA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

## Missed Dose:

If you missed your scheduled dose, contact your healthcare professional for advice.

## What are possible side effects from using ZOLADEX LA?

These are not all the possible side effects you may have when taking ZOLADEX LA. If you experience any side effects not listed here, tell your healthcare professional.

- trouble passing urine
- lower back pain
- hair loss, particularly the loss of body hair
- hot flushes and sweating
- reduced sex drive/impotence
- change in breast size
- skin rashes
- weight gain
- tingling in fingers or toes
- joint pain
- tender breasts

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Bone pain	✓		
Changes in blood pressure		✓	
Depression		✓	
<b>Diabetes:</b> rises in blood sugar levels, which may cause excessive thirst, excessive urination, excessive eating, unexplained weight loss, poor wound healing, infections		✓	
<b>Heart failure</b> (reduced heart function) <b>or heart attack:</b> shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Injection site reaction:</b> pain, bruising, bleeding, itching, redness, burning and swelling	✓		
<b>Osteoporosis</b> (thin, fragile bones): broken bones, pain, back pain that gets worse when standing or walking, thinning of bones		✓	
<b>UNCOMMON</b>			
<b>Allergic reactions:</b> fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes		✓	
<b>RARE</b>			
<b>Severe bleeding due to injection site injury, including damage to blood vessels in the abdomen:</b> bleeding underneath the skin or bruising, abdominal pain, abdominal distension, swelling at the injection site, shortness of breath, dizziness, low blood pressure and/or altered levels of consciousness		✓	
<b>VERY RARE</b>			
<b>Hallucinations:</b> seeing, feeling or hearing things that are not there, disordered thoughts or personality changes		✓	
<b>Pituitary tumours</b> (tumour of the pituitary gland in your head): headaches, vomiting, loss of eyesight and unconsciousness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

- Store ZOLADEX LA in its original pack between 2°C and 25°C.
- Keep out of reach and sight of children.
- ZOLADEX LA should not be used after the expiry date on the pack.

**If you want more information about ZOLADEX:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website: [www.tersera.ca](http://www.tersera.ca), or by calling 1-844-334-4035.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at [www.tersera.ca](http://www.tersera.ca).

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## PATIENT MEDICATION INFORMATION FOR BREAST CANCER AND ENDOMETRIOSIS

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **ZOLADEX® LA** **Goserelin Implant**

Read this carefully before you start taking **ZOLADEX® LA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZOLADEX LA**.

#### **Serious Warnings and Precautions**

ZOLADEX LA should be prescribed and managed by a healthcare professional experienced with using this type of drug.

ZOLADEX LA should be administered by a healthcare professional experienced in administering deep subcutaneous injections.

ZOLADEX LA may cause:

- worsening of tumour symptoms at the beginning of treatment;
- bone thinning (osteoporosis);
- injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of ZOLADEX LA. In rare cases this has caused severe bleeding (with some cases requiring surgical treatment).

#### **What is ZOLADEX LA used for?**

##### **Breast Cancer**

- The management of estrogen receptor (ER)-positive early breast cancer with a high risk of recurrence or advanced breast cancer in pre- and perimenopausal women.

##### **Benign Conditions (Non-cancerous)**

##### **Endometriosis**

- In women, ZOLADEX LA is used to treat endometriosis, including symptoms such as pain relief and reducing lesions (abnormal tissue growth). Endometriosis is a condition where the lining of the uterus grows in areas outside of the uterus.

#### **How does ZOLADEX LA work?**

ZOLADEX LA contains a medicine called goserelin. It belongs to a group of medicines called “Gonadotropin releasing hormone analogues”.

ZOLADEX LA works by reducing the amount of estrogen produced by your body.

#### **What are the ingredients in ZOLADEX LA?**

Medicinal ingredients: goserelin (as goserelin acetate)

Non-medicinal ingredients: Lactide-glycolide copolymer

#### **ZOLADEX LA comes in the following dosage forms:**

Implant: 10.8 mg

ZOLADEX LA comes in a hard, cream-coloured, rod-shaped implant.

**Do not use ZOLADEX LA if you:**

- are allergic to goserelin acetate or any of the ingredients in this medicine.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZOLADEX LA. Talk about any health conditions or problems you may have, including if you:**

- have or have had any problems passing urine
- have kidney problems
- have a family history of severe osteoporosis (a condition that affects the strength of your bones)
- have low bone mineral density
- take other medicines that cause thinning of the bones (such as corticosteroids or anti-seizure medicines)
- have a low red blood cell count (anemia)
- have heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using ZOLADEX LA.
- have had high blood pressure
- have had depression
- have diabetes
- are taking blood thinners
- have a low body mass index (less than 18.5). You may be at higher risk of injury to blood vessels when using ZOLADEX LA.

**Other warnings you should know about:**

- **Vaginal bleeding**
  - Your menstruation (period) should stop during treatment with ZOLADEX LA. If your period does not stop, contact your healthcare professional.
  - If you stop treatment with ZOLADEX LA, your menstrual cycle should start again. If you notice it is taking longer for your menstrual cycle to start or if it does not return within 12 weeks, contact your healthcare professional.
- **Pregnancy and birth control**
  - Do NOT become pregnant during treatment with ZOLADEX LA. It may harm your unborn baby.
  - Use non-hormonal birth control during treatment with ZOLADEX LA, such as a barrier method. Talk to your healthcare professional about birth control methods that may be right for you.
  - If you become pregnant during treatment with ZOLADEX LA, talk to your healthcare professional right away.
- **Breast-feeding**
  - Do NOT breast-feed during treatment with ZOLADEX LA. Talk to your healthcare professional about the best way to feed your baby during treatment.
- **Check-ups and testing**
  - You will have regular visits with your healthcare professional during treatment with ZOLADEX LA. They may:
    - do regular physical exams and lab tests;

- do blood tests to check your electrolyte, glucose and hormone levels;
- do an electrocardiogram (ECG) to check your heart health;
- check for signs of side effects.
- **Children (under 18 years of age)**
  - You should not be given ZOLADEX LA if you are under 18 years of age.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

**The following may interact with ZOLADEX LA:**

- medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);
- medicines that might increase the risk of heart rhythm problems when used with some other drugs, such as:
  - methadone (used for pain relief)
  - moxifloxacin (an antibiotic), and
  - antipsychotics (used for serious mental illnesses).

**How to take ZOLADEX LA:**

- ZOLADEX LA is injected under the skin on your abdomen by a healthcare professional. It is important that you continue ZOLADEX LA treatment, even if you are feeling well. Your healthcare professional will decide when it is time for you to stop.

**Usual dose:**

- Breast cancer: one injection every 12 weeks
- Endometriosis: one injection every 12 weeks

**Overdose:**

If you think you, or a person you are caring for, have taken too much ZOLADEX LA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you missed your scheduled dose, contact your healthcare professional for advice.

**What are possible side effects from using ZOLADEX LA?**

These are not all the possible side effects you may have when taking ZOLADEX LA. If you experience any side effects not listed here, tell your healthcare professional.

- a slight increase in the symptoms of fibroids, such as pain
- ovarian cysts (swelling), which may cause pain
- hot flushes and sweating
- reduced sex drive/impotence
- change in breast size
- skin rashes
- weight gain
- tingling in fingers and toes
- joint pain



Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Acne (often reported within one month of starting ZOLADEX LA)	✓		
Injection site reaction: pain, bruising, bleeding, itching, redness, burning and swelling	✓		
Vaginal dryness	✓		
COMMON			
Changes in blood pressure		✓	
Excessive nausea, vomiting or thirst	✓		
Hair loss (usually mild but occasionally severe)	✓		
Headache		✓	
Increased signs and symptoms of breast cancer		✓	
Mood changes including depression: difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide		✓	
Osteoporosis (thin, fragile bones): broken bones, pain, back pain that gets worse when standing or walking		✓	
UNCOMMON			
Allergic reactions: fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes		✓	
RARE			
Severe bleeding due to injection site injury, including damage to blood vessels in the abdomen: bleeding underneath the skin or bruising, abdominal pain, abdominal		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
distension, swelling at the injection site, shortness of breath, dizziness, low blood pressure and/or altered levels of consciousness			
<b>VERY RARE</b>			
<b>Hallucinations:</b> seeing, feeling or hearing things that are not there, disordered thoughts or personality changes		✓	
<b>Pituitary tumours</b> (tumour of the pituitary gland in your head): headaches, vomiting, loss of eyesight and unconsciousness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

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