PART III: CONSUMER INFORMATION

Pr Zoladex®

goserelin depot

This leaflet is part III of a three-part "Product Monograph" published when ZOLADEX® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZOLADEX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What ZOLADEX is used for:

Prostate Cancer

ZOLADEX is used:

- For the palliative treatment of patients with hormone-dependent advanced carcinoma of the prostate (Stage D2).
- In combination with a non-steroidal antiandrogen and radiation therapy for the management of locally advanced (T3, T4) or bulky Stage T2b, T2c carcinoma of the prostate.
- As adjuvant hormone therapy to external beam irradiation for patients with locally advanced prostate cancer (Stage T3-T4).

Breast Cancer

ZOLADEX is used:

- As an alternative to standard adjuvant chemotherapy in pre- and perimenopausal women with early breast cancer who are unsuitable for, intolerant to, or decline chemotherapy, and whose tumour contains estrogen and/or progesterone receptors.
- ZOLADEX is indicated for the palliative treatment of advanced breast cancer in pre- and perimenopausal women whose tumour contains estrogen and/or progesterone receptors.

Benign Conditions

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

ZOLADEX is indicated for use as an endometrial thinning agent prior to endometrial ablation.

What ZOLADEX does:

ZOLADEX treatment, given once every 28 days, results in suppression of your sex hormones (testosterone in men and estradiol in women).

When ZOLADEX should not be used:

You should not use ZOLADEX if:

- You are allergic to goserelin acetate or any nonmedicinal ingredients of in ZOLADEX.
- You are a woman who has abnormal vaginal bleeding for an unknown reason.
- You are a woman who is pregnant.
- You are a woman who is breastfeeding.

What the medicinal ingredient is:

goserelin acetate

What the important nonmedicinal ingredients are:

Lactide-glycolide copolymer

What dosage forms ZOLADEX comes in:

ZOLADEX comes in a hard, cream-coloured, rod-shaped depot which contains 3.6mg goserelin as goserelin acetate.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

ZOLADEX should be administered by a healthcare professional experienced in administering deep subcutaneous injections and under the supervision of a physician.

ZOLADEX may cause:

- Worsening of symptoms of prostate cancer at the beginning of the treatment (risk of spinal cord compression, or increased difficulty in urinating)
- Bone thinning (osteoporosis)
- Injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of ZOLADEX. In rare cases this has caused severe bleeding (with some cases requiring surgical treatment).

If you go into hospital, let the medical staff know you are receiving ZOLADEX.

In women, there are no clinical data on the effect of treating endometriosis with ZOLADEX for periods in excess of 6 months.

ZOLADEX is not recommended for use in children.

ZOLADEX is not recommended for use in very thin patients and/or those on blood thinners.

ZOLADEX is unlikely to affect your ability to drive a car or to operate machinery.

Before you use ZOLADEX, talk to your doctor or pharmacist if any of the following applies to you:

- Have or have had any problems passing urine.
- Family history of severe osteoporosis (thinning of the bones with fractures).
- Have low bone mineral density (BMD).
- Taking other medicines that cause thinning of the bones.
- Have a low red blood cell count (anemia)
- Have heart or blood vessel disease, have had an abnormal heart rhythm (QT prolongation), have a heart condition called 'long QT syndrome', a family history of this heart condition, or are being treated with medicines for these conditions. ZOLADEX may increase the risk of having an abnormal heart rhythm (QT prolongation).
- Have diabetes
- Are pregnant or planning to become pregnant. ZOLADEX should not be used during pregnancy, therefore, effective non-hormonal contraceptive methods should be used to prevent pregnancy during the treatment and until the return of menses after the last injection with ZOLADEX. After stopping ZOLADEX it may take longer for some women to experience menses. Rarely, some women may enter menopause. If 8 weeks have passed after the last ZOLADEX injection and you do not experience menses, talk to your doctor.
- Taking blood thinners.

INTERACTIONS WITH THIS MEDICATION

Check with your doctor or pharmacist before taking any other drugs, including non-prescription drugs (for colds, nausea, etc.). ZOLADEX might interfere with some medicines used to treat heart rhythm problems or might increase the risk of heart rhythm problems when used with some other drugs that can cause heart rhythm abnormalities.

PROPER USE OF THIS MEDICATION

Usual Dose

- ZOLADEX is given as an injection under the skin of the abdomen by a trained health care professional, such as a doctor or nurse.
- **Prostate or breast cancer:** one injection every 28 days.
- **Endometriosis:** one injection every 28 days.
- It is very important your doctor checks your progress at regular medical visits. Consult your doctor before you decide to change your treatment.
- If you need more information, ask your doctor.

Overdose

In case of drug overdose, contact a health care practitioner, 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 doctor for advice.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, side effects are sometimes experienced with ZOLADEX.

Contact your doctor or pharmacist if you experience any of these problems:

- Tingling in your fingers or toes.
- Psychiatric problems such as hallucinations, disordered thoughts or personality change. These have occasionally been reported.
- Injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of ZOLADEX. This can cause severe bleeding. Contact your doctor immediately if you experience any of the following symptoms: bleeding underneath the skin or bruising, abdominal pain, abdominal distension, swelling at the injection site, shortness of breath, dizziness, low blood pressure and/or any altered levels of consciousness.
- There have been occasional reports of side effects with pituitary tumours. You may develop a tumour of the pituitary gland in your head or, if you have an existing tumour of the pituitary gland, ZOLADEX may cause it to bleed or collapse. Pituitary tumours may cause headaches, vomiting, loss of eyesight and unconsciousness.
- A local skin reaction may occur at the injection site such as pain, bruising, bleeding, itching, redness, burning and swelling. These reactions generally are mild and disappear after a few days. If they get worse or do not go away, tell your doctor.
- **Cancer patients:** Contact your doctor immediately if you develop: severe increased pain, numbness or weakness of the limbs, or persistent difficulty in urinating (prostate cancer).

Use of ZOLADEX in Men

- When you first start receiving ZOLADEX you may feel some pain in your bones. If this happens tell your doctor and you may be given something for this.
- Very occasionally you may have trouble passing urine or experience lower back pain. If this happens, tell your doctor and you may be given something for this.
- You may experience hair loss, particularly the loss of body hair.

Use of ZOLADEX in Women

- For pre-menopausal women: menstruation stops with the monthly depot of ZOLADEX. If regular menstruation persists, notify your doctor. If a monthly ZOLADEX depot is missed, breakthrough menstrual bleeding may occur.
- Vaginal bleeding may occur. At the beginning of treatment, if you have fibroids a slight increase in symptoms, such as pain, may occur. These effects are usually short-lived and discontinue on continuation of treatment. If symptoms persist or you are uncomfortable, contact your doctor.
- Occasionally some women may enter menopause early, so when ZOLADEX treatment is stopped, menstruation will not start again.
- ZOLADEX has been associated with the formation of ovarian cysts, which may cause pain for some women.
- If you experience excessive nausea, vomiting or thirst, you should tell your doctor. This may indicate possible changes in the amount of calcium in your blood and your doctor may have to do certain blood tests.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
USE OF ZOLADEX IN MEN			
Very Common (more than 10 in every 100 patients are likely to have them)			
Reduced sex drive/impotence	√		
Hot flushes and sweating	√		
Common (1 to 10 in every 100 patients are likely to have them)			
Change in breast size	√		
Injection site reaction	√		
Depression		√	
Bone pain	√		
Rises in blood sugar levels		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Tingling in fingers or toes	√		
Changes in blood pressure		√	
Skin rashes	√		
Thinning of bones		√	
Heart failure (reduced heart function) or heart attack		√	
Weight gain	√		
Uncommon (1 to 10 in every 1000 patients are likely to have them)			
Tender breasts	√		
Joint pain		√	
Allergic reactions		√	
Rare (1 to 10 in every 10 000 patients are likely to have them)			
Severe bleeding due to injection site injury, including damage to blood vessels in the abdomen. Symptoms such as 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.		√	
USE OF ZOLADEX IN WOMEN			
Very Common (more than 10 in every 100 patients are likely to have them)			
Reduced sex drive	√		
Hot flushes and sweating	√		
Vaginal dryness	√		
Change in breast size	√		
Injection site reaction	√		
Acne*	√		
Common (1 to 10 in every 100 patients are likely to have them)			
Increased signs and symptoms of breast cancer		√	
Mood changes including depression		√	
Tingling in fingers and toes	√		
Headache		√	
Changes in blood pressure		√	
Skin rashes	√		
Thinning of bones		√	
Joint pain		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Hair loss (usually mild but occasionally severe)	√		
Weight gain	√		
Uncommon (1 to 10 in every 1000 patients are likely to have them)			
Allergic reactions		√	
Rare (1 to 10 in every 10 000 patients are likely to have them)			
Severe bleeding due to injection site injury, including damage to blood vessels in the abdomen. Symptoms such as 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.		√	

***** Often, acne is reported within one month after starting ZOLADEX.

This is not a complete list of side effects. For any unexpected effects while taking ZOLADEX, contact your doctor or pharmacist.

HOW TO STORE IT

- ZOLADEX should not be used after the expiry date on the pack. Store ZOLADEX in its original pack between 2°C and 25°C.
- If your doctor decides to stop your treatment, return ZOLADEX to the pharmacy for proper disposal.
- Keep your ZOLADEX in a safe place where children cannot reach it. It could harm them.

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.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION Leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information leaflet, plus the full Product Monograph prepared for health professionals can be found at:

www.tersera.ca, or by contacting the sponsor at:
Questions or concerns – 1-855-820-2141

This leaflet was prepared by:

TerSera Therapeutics LLC Lake Forest, IL 60045

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