

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

## Zoladex®

### Implant for subcutaneous injection in a pre-filled syringe

#### Composition:

Each syringe contains:

goserelin (as acetate) 3.6 mg

For inactive ingredients, please see section 6 – "Further Information".

#### **Read this leaflet carefully in its entirety before using this medicine.**

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

Most of the information in this leaflet applies to women and men.

When the information applies to men only, it will be labeled with the heading "Information for men".

When the information applies to women only, it will be labeled with the heading "Information for women".

#### **1. WHAT IS ZOLADEX AND WHAT IT IS INTENDED FOR?**

##### Information for men:

For treatment of prostate cancer. Zoladex works by lowering the levels of testosterone, a hormone produced by the body.

##### Information for women:

In women, Zoladex works by lowering the levels of estrogen, a hormone produced by the body.

- For treatment of breast cancer in premenopausal women.
- For treatment of endometriosis – a disease of the womb lining (a condition

where pain is caused by excess tissue which grows within or outside of the womb).

- Helps fertility by preparing for superovulation.
- Uterine fibroids (benign growths that appear in the womb), to decrease the size of fibroids before surgery.
- Prethinning of the womb lining before surgery.

**Therapeutic activity:**

Zoladex contains a medicine called goserelin. This belongs to a group of medicines called: LHRH analogues.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- You are sensitive to the active ingredient goserelin or to any of the other ingredients of the preparation (detailed in section 6 "Further Information").
- You are pregnant or breastfeeding (see section 2 "Pregnancy, breastfeeding and fertility").

Do not use Zoladex if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Zoladex.

**Special warnings regarding use of the medicine**

If you go to the hospital, please inform the medical staff that you are taking Zoladex.

**Before treatment with Zoladex, inform the doctor, pharmacist or nurse if:**

- You have high blood pressure.
- if you have any 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.
- You are suffering from a condition that affects the strength of bones, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones), have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

Medicines of this type may cause a reduction of calcium in the bones (thinning of bones).

There have been reports of depression in patients taking Zoladex which may be severe. If you are taking Zoladex and develop depressed mood, please inform your doctor.

### **Children and adolescents**

This medicine is not intended for children.

### Information for men:

Before treatment with Zoladex, inform the doctor, pharmacist or nurse if:

- you have problems passing urine or problems with your back.
- You have diabetes.

### Information for women:

Before treatment with Zoladex, inform the doctor, pharmacist or nurse if:

- Worsening of breast cancer symptoms may occur at the beginning of treatment, such as, increased pain and/or increased size of affected tissue. These effects are usually short-lived and pass with continued treatment. If the symptoms persist or if they cause discomfort, **refer to the doctor**.
- You are taking Zoladex to treat endometriosis, the doctor can lower the reduction in bone density caused by Zoladex by adding another treatment.

### **Drug interactions:**

**If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor, nurse or pharmacist.**

Zoladex might interfere the activity of some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with other drugs (e.g. methadone - used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses.

### **Pregnancy, breastfeeding and fertility**

- Do not take this medicine if you are pregnant or breastfeeding.
- Do not use this medicine if you are trying to become pregnant (unless Zoladex is being used as part of a treatment for infertility).

- Do not use oral contraceptives when taking Zoladex. Use barrier method of contraception, such as the condom or diaphragm.

### **Driving and using machines**

Zoladex does not usually have an effect on ability to drive a car or use tools and machines.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

- Always take this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with this medicine.
- The dosage and manner of treatment will be determined only by your doctor.  
**Do not exceed the recommended dosage.**
- Adhere to the treatment regimen as recommended by your doctor.

The recommended dosage is usually:

- The doctor or nurse will inject you the Zoladex implant on your stomach (under the skin) every four weeks (28 days).
- It is important that you keep having Zoladex treatment, even if you are feeling well, unless your doctor has decided to stop treatment.

### **Your next appointment**

- You should be given a Zoladex injection every 28 days.
- Always remind the doctor or nurse to set up an appointment for your next injection.
- If you are given an appointment for your next injection which is earlier or later than 28 days from your last injection, tell your doctor or nurse.
- If it has been more than 28 days since your last injection, contact your doctor or nurse so that you can receive your injection as soon as possible.

### **Information for women:**

- If Zoladex is being taken to treat uterine fibroids and you suffer from anemia (low levels of red blood cells or hemoglobin), the doctor may give you an iron supplement.
- The length of your treatment with Zoladex will depend on what you are having it for:
  - Treatment of uterine fibroids is limited to 3 months.

- If Zoladex is being taken to treat endometriosis, the duration of treatment is up to 6 months.
- Treatment for womb lining thinning before surgery is for one or two months (4 or 8 weeks).

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of this medicine, consult with your doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Zoladex may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

The following side effects can occur in men or women:

Allergic reactions

These are rare. The signs can include sudden onset of:

- Rash, itching and urticaria.
- Swelling of the face, lips or tongue or other parts of the body.
- Shortness of breath, wheezing or difficulties breathing.

If you experience these, **refer to the doctor immediately.**

Injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of Zoladex. In very rare cases this has caused severe bleeding. **Contact your doctor immediately** if you experience any of the following symptoms:

- Abdominal pain
- Abdominal distension
- Shortness of breath
- Dizziness
- Low blood pressure and/or any altered levels of consciousness

**Additional side effects:**

**Very common side effects (may affect more than 1 in 10 patients):**

- Hot flushes and sweating. Occasionally these side effects may continue for some time (possibly months) after stopping Zoladex.
- Reduced sex drive and impotence.
- Bruising, pain, bleeding, redness, swelling at the injection site.

**Common side effects (may affect up to 1 in 10 patients):**

- Pain in your lower back or problems passing urine. If this happens, **talk to your doctor.**
- Bone pain at the beginning of treatment. If this happens, **talk to your doctor.**
- Temporary worsening of symptoms of your cancer at the beginning of treatment.
- Decrease in bone density
- Rise in blood sugar levels
- Tingling in the fingers or toes
- Skin rash
- Hair loss
- Weight gain
- Pain in the joints
- Reduced heart function or heart attack
- Changes in blood pressure
- Swelling and tenderness of your breasts
- Changes in mood (including depression)

**Very rare side effects (may affect up to 1 in 10,000 patients):**

- Psychiatric problems called psychotic disorders which can be manifested by development of hallucinations (seeing, hearing or feeling things that are not there), disordered thoughts and personality changes. This is very rare.
- Development of a tumor in the pituitary gland, or, if a tumor in the pituitary gland already exists, Zoladex may cause the tumor to bleed or collapse. This effect is very rare. Tumors in the pituitary gland can cause severe headaches, nausea or vomiting, loss of eyesight, unconsciousness.

**Side effects with unknown frequency**

- Changes in your blood
- Liver problems including jaundice
- A blood clot in your lungs causing chest pain or shortness of breath

- Inflammation of the lung. The symptoms may be like pneumonia (such as feeling short of breath and coughing)
- Changes in ECG (QT prolongation)
- Memory impairment

Information for men:

The following side effects can occur in men

**Very common side effects (may affect more than 1 in 10 patients):**

- Impotence

**Common side effects (may affect up to 1 in 10 patients):**

- Pain in your lower back or problems passing urine. If this happens, **talk to your doctor**
- Bone pain at the beginning of treatment. If this happens, **talk to your doctor**
- Reduced heart function or heart attack
- Swollen and tender breasts
- Increased blood sugar levels

Information for women:

The following side effects can occur in women

**Very common side effects (may affect more than 1 in 10 patients):**

- Dryness of the vagina
- Changes in breast size
- Acne (reported very commonly, usually occurs within one month of beginning of treatment)

**Common side effects (may affect up to 1 in 10 patients):**

- Headaches (common)

**Rare side effects (may affect up to 1 in 1,000 patients):**

- Small cysts (swellings) may appear on the ovaries which may cause pain. They usually disappear without treatment.
- Some women may enter menopause earlier, such that, when treatment of Zoladex is discontinued, she will no longer menstruate.

**Side effects with unknown frequency:**

- Vaginal bleeding may occur. Usually happens in the first month of treatment. The bleeding should stop on its own. If the bleeding persists, **refer to the doctor.**
- If you have fibroids, there may be a slight increase in symptoms such as pain.

**When using Zoladex for the treatment of endometriosis, uterine fibroids, infertility or to thin the womb lining, the following effects may occur:**

- Changes in body hair
- Dry skin
- Weight gain
- Increased blood fats, known as cholesterol. This would be seen in a blood test
- Inflammation of the vagina and discharge from the vagina
- Nervousness
- Tiredness and disturbed sleep
- Swelling in the feet and ankle
- Muscle pain
- Sudden painful muscle tightness (cramp) in the legs
- Digestive system problems – nausea and vomiting, diarrhea and constipation
- Change in voice
- When Zoladex is used to treat uterine fibroids, a slight increase in the symptoms of fibroids, such as pain

**When Zoladex is given to treat breast cancer**

- worsening of breast cancer symptoms may occur at the beginning of treatment, such as, increased pain and/or increased size of affected tissue. These effects are usually short-lived and pass with continued treatment. If the symptoms persist or if they cause discomfort, **refer to the doctor.**
- If you suffer from a lot of nausea, vomiting or thirst, inform the doctor. These effects may indicate possible changes in the amount of calcium in the blood. **Refer to the doctor** as you may have to perform certain blood tests.

**When Zoladex is used to treat infertility with other gonadotrophins:**

- An over activity of the ovaries may happen and it may be manifested by: stomach pain, swelling of the abdomen, nausea or vomiting. If you suffer from any of these symptoms, **refer to the doctor.**



In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult the doctor immediately.

**If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult with your doctor.**

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

[https:// sideeffects.health.gov.il](https://sideeffects.health.gov.il)

### **5. HOW SHOULD THE MEDICINE BE STORED?**

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit doctor’s instruction.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Use immediately after opening the aluminum pouch.
- Do not store different medicines in the same package.
- Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Lactide/glycolide 50/50 copolymer

**What does the medicine look like and what are the contents of the package?**

The package contains one syringe with one dose (implant). The pre-filled syringe, ready to be used by the doctor or nurse. The syringe is in a closed aluminum pouch. The syringe has a safety mechanism and includes a device and a sleeve for injecting the medicine.

**Manufacturer:**

AstraZeneca UK Ltd., Macclesfield, UK.

**License holder and Importer and its address:**

AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140-16-25142-00

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