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

The dispensing of this medicine requires a doctor's prescription.

ZOLADEX® LA

Implant for subcutaneous injection in a pre-filled syringe

COMPOSITION

Each syringe contains:
goserelin (as acetate) 10.8 mg
For inactive ingredients, please see section 6 – Further information.

Read the package insert carefully in its entirety before using this medicine.
Keep this leaflet; you may need it again.
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.
If you have any of the side effect, or if you experience a side effects that is not mentioned in this leaflet, please contact your doctor immediately.
This medicine is not intended for women and children.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of prostate cancer.

Therapeutic group
Zoladex LA contains a medicine called goserelin. This belongs to a group of medicines called 'LHRH analogues'.
Zoladex LA is used to treat prostate cancer. It works by reducing the amount of 'testosterone' (a hormone) that is produced by your body. Zoladex LA is a long-acting form of Zoladex and it is given every 12 weeks.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:
you have previously had an allergic reaction to the active ingredient or to this type of medicine, or to any of the other ingredients in this product (see section 6).
Not to be used by women.
This medicine should not be given to children.

Special warnings regarding use of Zoladex
❗ Before treatment with Zoladex inform the doctor if:

- you are suffering or have suffered in the past from problems passing urine or from back problems.
- you suffer from diabetes.
- you suffer from high blood pressure.
- you have any condition that affects the strength of your 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) or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids). Medicines of this type can cause a reduction in bone calcium (thinning of bones).
- 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.
- There have been reports of depression in patients taking Zoladex which may be severe. If you are taking Zoladex and develop depressed mood, inform your doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
If you go into hospital, tell the medical staff that you are having Zoladex.

❗ Children
Zoladex LA is not intended for treatment in children.

❗ If you are taking other medicines
If you are taking another medicine, including non-prescription medicines and nutritional supplements, or if you have just finished treatment with another medicine, inform the attending doctor in order to prevent risks and lack of efficacy arising from drug interactions.

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 some other drugs that may cause heart rhythm problems (e.g. methadone - used for pain relief and part of drug addiction detoxification, moxifloxacin - an antibiotic, antipsychotics used for serious mental illnesses).

❗ Driving
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

- The Zoladex LA Implant will be injected under the skin on your stomach every 12 weeks. This will be done by the doctor or nurse.
- It is important that you keep having Zoladex treatment, even if you are feeling well, unless your doctor decided to stop treatment.

Dosage

- The medicine should be given every 12 weeks by your doctor or a nurse.
- Dosage is according to doctor's instructions only.
- Do not exceed the recommended dosage.
- This medicine is not intended for children and infants.
- This medicine is to be taken at specific time intervals as determined by the attending doctor.
- If it has been more than 12 weeks since your last injection, contact your doctor or nurse so that you can receive your injection as soon as possible.

4. SIDE EFFECTS

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

- rare allergic reactions (can be manifested as skin reactions such as rash, itching, urticaria, can cause swelling of the face [lips or tongue] or other body parts and can cause shortness of breath, wheezing and difficulty breathing). In case of allergic reactions, **refer to your doctor immediately.**

Injection site injury (including damage to blood vessels in the abdomen) has been reported following injection of Zoladex LA. In very rare cases this has caused severe bleeding. **Refer to the 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

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

- reduction of bone density
- swollen and tender breasts
- mood swings, including depression
- Bone pain at the beginning of treatment. If this happens, **refer to the doctor**
- problems with passing urine or lower back pain. If this happens, **refer to the doctor**
- tingling in fingers or toes
- skin rashes
- weight gain
- changes in blood pressure
- reduced heart function or heart attack
- increased blood sugar levels
- Occasionally mild bruising, pain, bleeding, redness, swelling may occur at the site of injection

Uncommon side effects (may affect up to 1 in 100 patients):

- pain in the joints

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

- Psychiatric problems called psychotic disorders, which may show themselves as development of hallucinations (seeing, hearing or feeling things that do not exists), disordered thoughts and personality changes, may occur very rarely.
- Development of a tumour in your pituitary gland, or if you have a tumour in your pituitary gland, Zoladex LA may make the tumour bleed. This is very rare effect. Tumour in the pituitary gland cause severe headaches, nausea, loss of eyesight and unconsciousness.

Side effects with frequency not known

- hair loss
- blood changes
- problems with liver function
- blood clot in the lungs which causes chest pain and shortness of breath
- pneumonia (symptoms such as shortness of breath or cough)
- Changes in ECG (QT interval prolongation)

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

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) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid Poisoning!** This medicine and all other medicines, must be stored in a safe place out of the sight and reach of children and/or infants, in order to avoid poisoning.
- 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 take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- Store the medicine in a cool place, not above 25°C, in the original package.
- Use immediately after opening the aluminum pouch.
- Do not store different medicines in the same package.

6. Further information

Composition: in addition to the active ingredient the medicine also contains Lactide/glycolide 95/5 copolymer (low and high molecular weight).

What the medicine looks like and what is the content of the package?
The package contains one syringe with one dose; 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.

Drug Registration No.: 105 61 28735 00

Manufacturer:
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This leaflet was checked and approved by the Ministry of Health in June 2017.

AstraZeneca

Reserved area