

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ZOLADEX® 10,8 mg Injection

Goserelin

Sugar free

Read all of this leaflet carefully before you start using ZOLADEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZOLADEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZOLADEX is and what it is used for
2. What you need to know before you use ZOLADEX
3. How to use ZOLADEX
4. Possible side effects
5. How to store ZOLADEX
6. Contents of the pack and other information

1. What ZOLADEX is and what it is used for:

ZOLADEX is a member of the anti-hormonal group of medicines. This means that it affects the levels of various hormones (natural chemicals produced by the body). In men it will reduce levels of the male hormone, testosterone. In women it will reduce the levels of the female hormone, oestrogen.

In men:

Used for the treatment of prostate cancer.

In women:

- Used to treat the symptoms associated with endometriosis (severe pain and discomfort that occurs at the start and during your period).
- Used to reduce fibroids in the womb before surgery.
- Used in pre-menopausal women to treat breast cancer that is sensitive to oestrogen.

2. What you need to know before you use ZOLADEX:

Do not use ZOLADEX:

- If you are hypersensitive (allergic) to goserelin or any of the other ingredients of ZOLADEX (list in section 6).
- If you are pregnant or breastfeeding.
- ZOLADEX should not be given to children.

Warnings and precautions

If you go into hospital, let the healthcare professional know you are receiving ZOLADEX.

Tell your doctor or health care provider before being given the injection:

In men:

- If you have any problems passing urine or if you have had any lower back problems.
- If you have high blood sugar.

In women:

- If you suffer from any condition that affects your bones.
- If you have been told that you suffer from polycystic ovarian syndrome.

Take special care during your treatment with ZOLADEX:

In women:

- You should not be using hormonal forms of contraception such as the “pill” or depot injection etc. You should use other forms of contraception such as the condom and diaphragm (cap).

- You may enter into menopause and your periods (menses) may not return when you stop receiving ZOLADEX 10,8 mg.
- Medicines of this type can cause a small loss of calcium from the bones (thinning of the bones). Some recovery of this loss can occur when treatment is stopped.
- If you are suffering from any disease which affects the strength of your bones, please make sure that your doctor, pharmacist or other health care professional is aware of this.
- If you are being treated for endometriosis, your doctor may reduce the thinning of the bones caused by ZOLADEX by giving you additional treatment.

In men:

- You may experience an increase in bone pain or severe back pains, if this happens contact your doctor.
- Your doctor may reduce the thinning of the bones caused by ZOLADEX by giving you additional treatment.

Other medicines and ZOLADEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breast feeding:

Do not use ZOLADEX if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines:

ZOLADEX is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent ZOLADEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOLADEX affects them.

Taking other medicines with ZOLADEX:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

3. How to use ZOLADEX

Your doctor or nurse will give you the ZOLADEX injection.

If you have the impression that the effect of ZOLADEX is too strong or too weak, tell your doctor or pharmacist.

The usual dose is for adult men, including the elderly, and those patients with kidney or liver problems is one ZOLADEX 10,8 mg injected under the skin in the stomach wall, every 3 months.

The usual dose for adult women including the elderly, and those patients with kidney or liver problems is one ZOLADEX 10,8 mg injected under the skin in the stomach wall, every 12 weeks.

It is important that you carry on receiving your ZOLADEX injection even if feeling well, unless your doctor decides it is time for your therapy to stop.

4. POSSIBLE SIDE EFFECTS:

ZOLADEX can have side effects.

Not all side effects reported for ZOLADEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ZOLADEX, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue and/or throat (also called angioedema)
- Itchy rash, welts and swelling of the skin (also called urticaria)

This is a very serious side effect. If you have it, you may have had a serious allergic reaction to ZOLADEX. You may need urgent medical attention or hospitalisation. This very serious side effect occurs infrequently.

Tell your doctor if you notice any of the following side effects:

Frequent:

- Reduced sex drive
- Hot flushes and sweating

In men:

- Tingling in fingers and toes
- Thinning of bones and increase in bone pain
- Swelling of breasts
- Skin rashes

In women:

- Headaches
- Change in breast size and dryness of the vagina
- Swollen or tender breasts
- Changes in blood pressure

Less Frequent:

In men:

- Pains in muscles and joints
- Trouble passing urine or lower back pain
- Breast tenderness

- If you have a tumour in your pituitary gland, ZOLADEX may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness.

In women:

- Formation of a cyst in the ovaries

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other health care professional.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ZOLADEX.

5. How to store ZOLADEX

Your doctor or the hospital will store the ZOLADEX injection.

Keep the injection in its original pack and do not break the seal, in order to protect it from light.

The injection should not be used after the expiry date on the pack.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ZOLADEX contains

The active substance is goserelin.

The other ingredients are a blend of high and low molecular weight lactide/glycolide copolymers and glacial acetic acid.

What ZOLADEX looks like and contents of the pack

White to cream coloured cylindrical pieces of rigid polymeric material, free or practically free from visible impurities.

The injections are supplied as a pre-loaded single-dose disposable syringe applicator.

Holder of Certificate of Registration

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