1.3.2.1 PATIENT INFORMATION LEAFLET - APPROVED

Patient Information Leaflet: ZOLADEX 3,6 mg Injection

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS: **S4**

PROPRIETARY NAME (and dosage form):

Zoladex® 3,6 mg (Injection)

The active substance is goserelin.

1. WHAT ZOLADEX 3,6 mg CONTAINS:

Each ZOLADEX 3,6 mg injection contains 3,6 mg of goserelin.

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

2. WHAT ZOLADEX 3,6 mg 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 breast cancer.
- Used to treat the symptoms associated with endometriosis (severe pain and discomfort that occurs at the start and during your period).
- Used to reduce the size of fibroids in the womb before surgery.
- Used for the treatment of endometrial thinning which is the severe bleeding of the uterus without performing surgery immediately.
- Used to aid in falling pregnant.

3. BEFORE YOU USE ZOLADEX 3,6 mg:

Do not use ZOLADEX 3,6 mg:

- If you are hypersensitive (allergic) to goserelin or any of the other ingredients of ZOLADEX.

- ZOLADEX should not be given to children.

Take special care with ZOLADEX 3,6 mg:

Before using ZOLADEX tell your doctor, pharmacist or other health care professional:

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

In men:

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

In women:

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

While you are taking ZOLADEX 3,6 mg:

In women:

- During your treatment with ZOLADEX 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 taking ZOLADEX 3,6 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 of other health care professional is aware of this. If you are being treated for enodmetriosis, 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.

Pregnancy and breast feeding:

Do not use ZOLADEX if you are pregnant or breast feeding.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

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

Taking other medicines with ZOLADEX 3,6 mg:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ZOLADEX with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

4. HOW TO USE ZOLADEX 3,6 mg:

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, talk to your doctor or pharmacist.

Adults, including the elderly, and those patients with kidney or liver problems:

One ZOLADEX 3,6 mg injected under the skin in the stomach wall every 28 days.

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

If you take more ZOLADEX 3,6 mg than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take ZOLADEX 3,6 mg:

Contact your doctor immediately.

5. POSSIBLE SIDE-EFFECTS:

ZOLADEX can have side-effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

Hypersensitivity, including swelling of the face, lips, tongue and/or throat (angioedema) and itchy rash, weals and swelling of the skin (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 is rare (less than 1 in every 1000 patients is likely to have it).

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

Very common (more than 10 of every 100 patients have these events):

- Reduced sex drive
- Hot flushes and sweating

In men:

- Tingling in fingers and toes.

In women:

- Headaches
- Change in breast size and dryness of the vagina.
- Changes in blood pressure

Common (1 to 10 of every 100 patients have these events):

In men:

- Thinning of bones and increase in bone pain.
- Swelling of breasts.
- Skin rashes

In women:

- Swollen or tender breasts.

Uncommon (less than 1 of every 100 but more than 1 of every 1000 patients are likely to have them):

In men:

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

- Breast tenderness

Rare (less than 1 per 1000 patients are likely to have them):

In men:

- 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.

6. STORING AND DISPOSING OF ZOLADEX 3,6 mg:

Your doctor or the hospital will store the ZOLADEX 3,6 mg 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.

Keep all medicines out of reach of children.

How to dispose of ZOLADEX 3,6 mg?

The hospital staff is responsible for disposing of the ZOLADEX 3,6 mg injection.

7. PRESENTATION OF ZOLADEX 3,6 mg:

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

8. IDENTIFICATION OF ZOLADEX 3,6 mg:

White to cream coloured cylindrical pieces of rigid polymeric material.

The depot is supplied in a pre-loaded single-dose disposable syringe applicator.

9. REGISTRATION NUMBER:

U/21.10/163

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West,

Bryanston, Johannesburg

2191, South Africa

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