

# Zoladex<sup>®</sup> 3.6 mg

## Goserelin acetate, 3.6 mg, injectable implant

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Zoladex 3.6**. It does not contain all the information that is known about **Zoladex 3.6**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Zoladex 3.6** against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

#### What Zoladex 3.6 is used for

**Zoladex 3.6** is a special preparation of goserelin acetate which is designed to work in the body for 28 days after each injection. **Zoladex 3.6** 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 women, female hormones make the breasts grow, prepare the womb and other sex organs for pregnancy, and increase the sex drive.

In men, male hormones make the testicles grow, assist an erection, and increase the sex drive.

When **Zoladex 3.6** lowers sex hormones, all these actions will be reduced. Due to the action of **Zoladex 3.6** on hormones, **Zoladex 3.6** can treat very different illnesses in both men and women.

#### **MEN:**

##### **Prostate Cancer**

**Zoladex 3.6** can treat prostate cancer in some men. It is not a cure for prostate cancer, and does not work in every patient with prostate cancer.

#### **WOMEN:**

##### **Breast Cancer**

**Zoladex 3.6** is used to treat hormone sensitive breast cancer in women before menopause. It is not a cure for breast cancer. It can often keep the cancer controlled for a period of time.

##### **Endometriosis**

For endometriosis, **Zoladex 3.6** may be used instead of surgery. **Zoladex 3.6** is not a cure for endometriosis. **Zoladex 3.6** may be helpful by reducing:

- “patches” of endometriosis tissue in the abdomen and pelvic area.
- the symptoms of endometriosis, including pain.

Endometriosis has no connection with any type of cancer.

##### **Uterine Fibroids**

Fibroids are growths in the womb which are not cancer.

For fibroids, **Zoladex 3.6** may be used before surgery. **Zoladex 3.6** is not a cure for uterine fibroids and may be helpful by reducing:

- the size of fibroids in or around the womb

- symptoms of fibroids including pain.

**Women who are receiving Zoladex 3.6 for endometriosis or fibroids are not being treated for cancer. If you want more information about this ask your doctor or pharmacist.**

### ***Endometrial Thinning***

**Zoladex 3.6** can be used to thin the lining of the womb before surgery to remove the lining. This treatment is used for some types of unusual bleeding from the womb.

### ***Infertility/Assisted Reproduction***

**Zoladex 3.6** can be used in combination with other medicines to control the release of eggs from the ovary as part of a treatment for infertility.

Your doctor may have prescribed **Zoladex 3.6** for another reason. Ask your doctor if you have any questions about why **Zoladex 3.6** has been prescribed for you.

**Zoladex 3.6** is not addictive.

**Zoladex 3.6** is only available with a doctor's prescription.

## **Before you use Zoladex 3.6**

### ***You must tell your doctor:***

**1. If you intend to become pregnant or plan to breast feed.**

Do not use **Zoladex 3.6** if you are pregnant, are trying to get pregnant, (except where **Zoladex 3.6** is used as part of a treatment for infertility) or while breastfeeding.

**2. If you have risk factors for loss of bone calcium and osteoporosis.** These factors include:

- smoking
- having a slight build
- having a diet low in calcium
- having treatment with steroids for other conditions
- poor mobility (for example, confined to a wheelchair).

When women are treated with **Zoladex 3.6**, the amount of calcium in their bones decreases over a period of months. Some recovery of this loss can occur when treatment has stopped. A similar condition also happens after the change of life, when the natural production of female sex hormones falls. The link between the loss of calcium while on **Zoladex 3.6** and the loss of calcium after the change of life (menopause) is uncertain. However, women who have a family history of osteoporosis and other risk factors should discuss the use of **Zoladex 3.6** with their doctor before using **Zoladex 3.6**.

**3. If you have had an allergy to any other medicines or any other substances, such as preservatives or dyes.**

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

**5. If you have diabetes.**

6. If you have any of the following: 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 in such patients when using **Zoladex 3.6**.

If you have not told your doctor about any of the above, tell him/her before you receive any **Zoladex 3.6**.

### ***Taking Other Medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.**

**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 medicines that can cause heart rhythm abnormalities.

### ***When you must not use it***

Do not use **Zoladex 3.6** if:

- **You are pregnant, could be pregnant or plan to get pregnant** unless you are receiving it as part of a treatment for infertility or have been specially advised by your doctor.
- **You are breastfeeding.**
- If you are breast feeding you should discuss this with your doctor.
- You have ever had an allergic reaction to **Zoladex 3.6**.
- The packaging is torn or shows signs of tampering.
- **The expiry date on the pack has passed.** If you receive this medicine after the expiry date has passed, it may not work.

**Zoladex 3.6** is not to be used in children.

### **Using Zoladex 3.6**

**Zoladex 3.6** will be given to you as an injection by your doctor or nurse. **Zoladex 3.6** comes in a special syringe and needle. A small pellet containing **Zoladex 3.6** is injected under the skin. The injection is often at the front of the stomach (belly), or to the side of the stomach.

The small pellet containing **Zoladex 3.6** is about the size of a grain of rice. After the pellet is injected, it slowly dissolves and releases **Zoladex 3.6**. Each pellet takes about 4 weeks (28 days) to dissolve completely. By four weeks, almost all the **Zoladex 3.6** is gone and has been used by the body. The pellet gives you a dose of **Zoladex 3.6** so you are certain to get your treatment.

Each dose of **Zoladex 3.6** comes in a new syringe and needle.

The number of injections with **Zoladex 3.6** will depend on the illness being treated. Your doctor will tell you how long you may need to receive **Zoladex 3.6**.

The usual length of treatment for endometriosis or fibroids is up to 6 months. If longer courses of treatment are needed, the doctor may need to consider possible side effects related to loss of calcium in bones.

The usual length of treatment for thinning of the womb lining is either one injection followed by surgery four weeks later or 2 injections spaced 4 weeks apart with surgery timed within zero to two weeks of the second injection.

### ***If You Miss A Treatment***

Tell your doctor if you miss your monthly treatment with **Zoladex 3.6**. If you have missed a dose on purpose because you do not like a side effect of the medicine discuss this with your doctor. Talk to your doctor if you want to stop receiving **Zoladex 3.6** because of side effects or for any other reason.

### **While you are using Zoladex 3.6**

#### ***Things you must do***

Make sure to keep your appointments for your **Zoladex 3.6** dose every 4 weeks. If you do not, your hormone level will rise and your illness may get worse.

While receiving **Zoladex 3.6** therapy, for uses other than infertility treatment, barrier methods of contraception such as the condom or diaphragm (cap) should be used. Oral forms of contraception (the "Pill") should not be taken when receiving **Zoladex 3.6**.

**If you become pregnant while receiving Zoladex 3.6, tell your doctor immediately.**

If you go into hospital, let the medical staff know you are receiving **Zoladex 3.6**.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are receiving **Zoladex 3.6**.

You should only stop receiving **Zoladex 3.6** if advised to do so by your doctor.

It is unlikely that **Zoladex 3.6** will affect your ability to drive a car or to operate machinery.

If you are unsure about any of these points or have further questions please tell your doctor or pharmacist.

### **Overdose**

Getting too much **Zoladex 3.6** is unlikely as overdose is getting more than one **Zoladex 3.6** treatment in 4 weeks (28 days).

If a person got more than one dose in 4 weeks, **Zoladex 3.6** would act for a bit longer. Tell your doctor if you think you have received too much **Zoladex 3.6**.

**Telephone your doctor or the National Poisons Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Zoladex 3.6. Even if there are no signs of discomfort or poisoning.**

### **Side effects**

Do not be alarmed by the following list of possible side effects. You may not experience any of them. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using **Zoladex 3.6**.

**Zoladex 3.6** helps most people with endometriosis, fibroids, some types of unusual bleeding from the womb, breast cancer or prostate cancer, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you have.**

**Tell your doctor if you notice any of the following and they worry you.**

- rare allergic reactions
- skin rashes
- painful joints
- tingling in fingers or toes
- changes in blood pressure
- thinning of bones

Pain, bruising, bleeding, redness, swelling and other reactions may occur around the site of injection.

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.

In the very rare case, when patients receiving **Zoladex 3.6** have a tumour in their pituitary gland, **Zoladex 3.6** may make the tumour bleed or collapse. This can cause severe headaches, sickness, loss of eyesight and unconsciousness.

These are side effects in both men and women.

***MEN:***

Sometimes side effects may be symptoms of the prostate cancer you are being treated for. Therefore you should always tell your doctor if you notice any possible side effect.

You may have a reduced sex drive. You may not be able to get an erection or father a child.

However, **Zoladex 3.6** is not a contraceptive for men and should never be used that way.

You may get hot flushes, sweating and weight gain. Some men may get swollen or tender breasts.

The testicles may become smaller. Mood swings have been commonly reported.

When you first start receiving **Zoladex 3.6** 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.

***WOMEN:***

Most women get signs of the change of life (menopause) while on **Zoladex 3.6** such as:

- change in libido (sex drive)
- hot flushes and sweating
- mood changes, including depression
- a change of breast size
- headache
- a dry vagina
- weight gain
- hair loss
- acne

Formation of ovarian cysts may occur, which may result in pain in some women.

**Zoladex 3.6** will usually stop your periods. Some women will have a menstrual period in the first 2 weeks after the first injection of **Zoladex 3.6**. Rarely, some women may enter their natural menopause when being treated with **Zoladex 3.6** and will not resume having periods when the treatment with **Zoladex 3.6** stops.

At the beginning of treatment, a worsening of symptoms of your breast cancer such as an increase in pain and/or an increase in the size of the affected tissue may occur. Vaginal bleeding may occur. 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. In addition, 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.

**If you are receiving Zoladex 3.6 for breast cancer it can be hard to tell the difference between unwanted effects due to Zoladex 3.6 and problems due to the cancer. Discuss any changes in your condition with your doctor.**

When **Zoladex 3.6** is being used as part of a treatment for infertility, the sex hormones, which are given to you later, may occasionally result in over-stimulation of the ovaries. If you experience abdominal pain, abdominal swelling, nausea or vomiting after receiving these drugs for such treatment you should let your doctor know immediately.

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Zoladex 3.6**.

#### After using Zoladex 3.6

##### **Storage**

**Keep your Zoladex 3.6 in the original packet.** Let only your doctor or nurse break the seal. Keep in a cool, dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines. **Keep it where children cannot reach it.** A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

##### **Disposal**

Once your doctor has given you the **Zoladex 3.6** Implant, he or she will dispose of the syringe and needles. If your **Zoladex 3.6** has passed its expiry date, ask your doctor or pharmacist how to dispose of it.

#### Product description

##### **What Does It Look Like**

**Zoladex 3.6** comes in a special syringe and needle known as SafeSystem. The small pellet containing **Zoladex 3.6** is about the size of a grain of rice. This pellet is located inside the syringe. **Zoladex 3.6** comes in packs of one injection.

##### **Ingredients**

**Zoladex 3.6** contains goserelin acetate. The pellet is made of a combination of two white or cream coloured substances called polyglactins.

**Marketed by:**

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