

Zoladex[®] 10.8 mg

Goserelin acetate, 10.8 mg, injectable implant

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Zoladex 10.8**. It does not contain all the information that is known about **Zoladex 10.8**.

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 10.8** 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 10.8 is used for

Zoladex 10.8 is a special preparation of goserelin acetate which is designed to work in the body for 12 to 13 weeks after each injection. Most people will need one injection for each 12 to 13 weeks of treatment. **Zoladex 10.8** is otherwise similar to Zoladex 3.6 mg which you may have received in the past. Zoladex 3.6 mg lasts for only 28 days.

Zoladex 10.8 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 10.8** lowers sex hormones, all these actions will be reduced. Due to the action of **Zoladex 10.8** on hormones, **Zoladex 10.8** can treat very different illnesses in both men and women.

MEN:

Prostate Cancer

Zoladex 10.8 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:

Endometriosis

For endometriosis, **Zoladex 10.8** may be used instead of surgery. **Zoladex 10.8** is not a cure for Endometriosis. **Zoladex 10.8** 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 10.8** may be used before surgery. **Zoladex 10.8** 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 10.8 for endometriosis or fibroids are not being treated for cancer. If you want more information about this ask your doctor or pharmacist.

Your doctor will help you understand the benefits of having **Zoladex 10.8** for your particular problem. Ask your doctor for further information if he/she has prescribed this medicine for a different purpose.

Zoladex 10.8 is not addictive.

Zoladex 10.8 is only available with a doctor's prescription.

Before you use Zoladex 10.8

You must tell your doctor:

1. **If you intend to become pregnant or plan to breast feed.**
Do not use **Zoladex 10.8** if you are pregnant, are trying to get pregnant, 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 10.8**, the amount of calcium in their bones decreases over a period of months. Some recovery of this loss can occur when treatment is 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 10.8** 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 10.8** with their doctor before using **Zoladex 10.8**.

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 10.8**.

If you have not told your doctor about any of the above, tell him/her before you receive any **Zoladex 10.8**.

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 10.8** 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 10.8**.
- 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 10.8 is not to be used in children.

Using Zoladex 10.8

Zoladex 10.8 will be given to you as an injection by your doctor or a nurse.

Zoladex 10.8 comes in a special syringe and needle. A small pellet containing **Zoladex 10.8** is injected under the skin. The injection is often at the front of the stomach or to the side of the stomach.

The injection leaves a small pellet underneath your skin. This pellet is designed to give you a dose of **Zoladex 10.8** which is released over 12 to 13 weeks. This means your injection will be given every 12 to 13 weeks. Your doctor will tell you for how long you may need to take **Zoladex 10.8**. It is important that you carry on receiving your **Zoladex 10.8** even if feeling well unless your doctor decides it is time for the treatment to stop.

Women should only receive **Zoladex 10.8** for a maximum of 6 months.

If you miss a treatment:

You should not delay or miss your 12 or 13 weekly **Zoladex 10.8**. This may lead to the treatment not working.

Tell your doctor if you miss your 12 or 13 weekly treatment of Zoladex 10.8. If you have missed a dose on purpose because you do not like a side effect of the injection, discuss this with your doctor. Talk to your doctor if you do not want to receive any more **Zoladex 10.8** injections because of side effects or for any other reason.

While you are using Zoladex 10.8

Things you must do

Make sure to keep your appointments for your **Zoladex 10.8** dose every 3 months.

If you are a woman receiving therapy with Zoladex 10.8, 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 10.8**. **If you become pregnant while receiving Zoladex 10.8, tell your doctor immediately.**

If you go into hospital, let the medical staff know you are receiving **Zoladex 10.8**.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are receiving **Zoladex 10.8**

You should only stop receiving **Zoladex 10.8** if advised to do so by your doctor.

It is unlikely that **Zoladex 10.8** 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 10.8** is unlikely as overdose is getting more than one **Zoladex 10.8** injection in 12 or 13 weeks. If a person received more than one injection in 12 or 13 weeks, **Zoladex 10.8** would act for a bit longer. Tell your doctor if you think you have received too much **Zoladex 10.8**.

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 10.8. 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. **Zoladex 10.8** begins to work in the two weeks after the first injection. You should expect to notice changes in your body because your sex hormones will fall to low levels.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using **Zoladex 10.8**.

Zoladex 10.8 helps most people with endometriosis, fibroids, 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 10.8** have a tumour in their pituitary gland, **Zoladex 10.8** 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 low sex drive during treatment with **Zoladex 10.8**. You may not be able to get an erection or father a child. However, **Zoladex 10.8** is not a contraceptive for men and should never be used in 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 10.8** 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 10.8** 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 10.8 will usually stop your periods. Some women will have a menstrual period in the first 2 weeks after the first injection of **Zoladex 10.8**. Rarely, some women may enter their natural menopause when being treated with **Zoladex 10.8** and will not resume having periods when the treatment with **Zoladex 10.8** stops. In some women, the time it takes for periods to begin again after they stop receiving **Zoladex 10.8**, can be prolonged.

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.

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 10.8**.

After using Zoladex 10.8

Storage

Keep your Zoladex 10.8 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 10.8** Implant, he or she will dispose of the syringe and needles. If your **Zoladex 10.8** has passed its expiry date, ask your doctor or pharmacist how to dispose of it.

Product description

What it looks like:

Zoladex 10.8 comes in a special syringe and needle known as SafeSystem™. The small pellet containing **Zoladex 10.8** is about the size of a grain of rice. This pellet is located inside the syringe. **Zoladex 10.8** comes in packs of one injection.

Ingredients:

Zoladex 10.8 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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