ZOLADEX® 10.8 mg Implant SafeSystem®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZOLADEX 10.8 mg?

ZOLADEX 10.8 mg contains the active ingredient goserelin acetate. ZOLADEX 10.8 mg is used to lower the amount of sex hormones in the body. ZOLADEX 10.8 mg is used to treat breast cancer in some women before menopause and prostate cancer in some men.

For more information, see Section 1. Why am I using ZOLADEX 10.8 mg? in the full CMI.

2. What should I know before I use ZOLADEX 10.8 mg?

Do not use if you have ever had an allergic reaction to goserelin acetate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ZOLADEX 10.8 mg? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZOLADEX 10.8 mg and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ZOLADEX 10.8 mg?

A ZOLADEX 10.8 mg implant will be injected into the skin of your stomach every 3 months.

More instructions can be found in Section 4. How do I use ZOLADEX 10.8 mg? in the full CMI.

5. What should I know while using ZOLADEX 10.8 mg?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ZOLADEX 10.8 mg.

	• Make sure to keep your appointment for being given ZOLADEX 10.8 mg every 3 months. • Use non-hormonal contraceptive methods while having ZOLADEX 10.8 mg treatment.
Things you should not do	• Do not stop being given ZOLADEX 10.8 mg unless you have discussed it with your doctor first. • Do not use hormonal contraceptives while being treated with ZOLADEX 10.8 mg.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ZOLADEX 10.8 mg affects you.
Looking after your medicine	• Keep in a cool, dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using ZOLADEX 10.8 mg? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor immediately if you have trouble passing urine, feel weak in the arms or legs, feel numb in the arms or legs, have pain in the kidneys, have pain in the bones or backbone or have a tumour in your pituitary gland which causes severe headaches, sickness, loss of eyesight and unconsciousness. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ZOLADEX® 10.8 mg Implant SafeSystem®

Active ingredient: *goserelin acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOLADEX 10.8 mg. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZOLADEX 10.8 mg.**

Where to find information in this leaflet:

1. Why am I using ZOLADEX 10.8 mg?
2. What should I know before I use ZOLADEX 10.8 mg?
3. What if I am taking other medicines?
4. How is ZOLADEX 10.8 mg given?
5. What should I know while using ZOLADEX 10.8 mg?
6. Are there any side effects?
7. Product details

1. Why am I using ZOLADEX 10.8 mg?

ZOLADEX 10.8 mg contains the active ingredient goserelin acetate. ZOLADEX 10.8 mg 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 women, it reduces the level of oestrogen. In men it reduces the level of testosterone.

Use of ZOLADEX 10.8 mg in women

ZOLADEX 10.8 mg can treat breast cancer in some women before menopause. It is not a cure for breast cancer.

Use of ZOLADEX 10.8 mg in men

ZOLADEX 10.8 mg is used to treat prostate cancer in some men. It is not a cure for prostate cancer.

2. What should I know before I use ZOLADEX 10.8 mg?

Warnings

Do not use ZOLADEX 10.8 mg if:

- you are allergic to goserelin acetate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include:

- rash
- itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath
- wheezing or difficulty breathing

- feeling faint, dizziness, lightheaded

Check with your doctor if you:

- have any other medical conditions (have heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions). The risk of you having further heart rhythm problems may increase if you are taking ZOLADEX 10.8 mg.
- have any condition which affects the strength of your bones.
- have had any problems passing urine or if you have had any lower back problems.
- have diabetes.
- take any medicines for any other conditions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use ZOLADEX 10.8 mg while you are pregnant. It may affect the baby. It is not known if ZOLADEX 10.8 mg passes into breast milk. It is unlikely that you can father a child or become pregnant while using

ZOLADEX 10.8 mg. However, non-hormonal methods of contraception, such as the condom or diaphragm, should be used.

Children

Do not give ZOLADEX 10.8 mg to children.

There is no information on its use in children.

3. What if I am taking other medicines?

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

ZOLADEX 10.8 mg 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 drugs that can cause heart rhythm abnormalities.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZOLADEX 10.8 mg.

4. How is ZOLADEX 10.8 mg given?

How much you will be given

- A ZOLADEX 10.8 mg implant will be injected into the skin of your stomach every 3 months.

- The implant is a very small pellet that is given by a special needle and syringe known as SafeSystem. The injection will not hurt very much.
- The pellet is designed to slowly release the medicine into your body over 3 months.
- The ZOLADEX 10.8 mg SafeSystem incorporates a protective needle sleeve that automatically locks in place following administration of the implant to help prevent needle stick injury.

How long to use ZOLADEX 10.8 mg

- The length of time you will use ZOLADEX 10.8 mg for depends on what illness is being treated.
- Your doctor will tell you how long you will need to be given ZOLADEX 10.8 mg.

If you forget to be given ZOLADEX 10.8 mg

Your doctor will make an appointment for your next dose, so you will not forget your next dose.

If you use too much ZOLADEX 10.8 mg

The doctor or nurse giving you ZOLADEX 10.8 mg will be experienced in the use of it, so it is unlikely that you will be given an overdose.

5. What should I know while using ZOLADEX 10.8 mg?

Things you should do

Make sure to keep your appointment for being given ZOLADEX 10.8 mg every 3 months.

If you do not, your hormone level will rise and your illness may get worse.

Use non-hormonal contraceptive methods (e.g. condom or diaphragm) while having ZOLADEX 10.8 mg treatment.

Tell your doctor immediately if you become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using ZOLADEX 10.8 mg.

Things you should not do

- **Do not stop being treated with ZOLADEX 10.8 mg unless you have discussed it with your doctor first.**

  Your doctor will have explained why you need to be given ZOLADEX 10.8 mg and for how long.

- **Do not use hormonal contraceptives while being treated with ZOLADEX 10.8 mg.**

  They interfere with the way it works.

- **Do not use if the packaging is torn or shows signs of tampering.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZOLADEX 10.8 mg affects you.

Looking after your medicine

Keep your ZOLADEX 10.8 mg in the package until you take it to the doctor or nurse to give it to you.

If you take ZOLADEX 10.8 mg out of the pack, you may dislodge the pellet in the syringe.

Keep in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Tell your doctor immediately if any of these things happen while you are using ZOLADEX 10.8 mg: • have trouble passing urine • feel weak in the arms or legs • feel numb in the arms or legs • have pain in the kidneys • have pain in the bones or backbone	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
The side effects listed above may mean that the cancer is growing. • Signs of an injection site injury which may be associated with severe bleeding, such as abdominal pain, abdominal distension, shortness of breath, dizziness, low blood pressure and/or any altered levels of consciousness • signs of an allergic reaction such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing; fainting, dizziness, feeling lightheaded. • symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst,	

Serious side effects	What to do
increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell) • chest pain • signs of cardiac failure such as shortness of breath, extreme tiredness, swelling in the legs, ankles, and feet, and persistent coughing or wheezing • If you have a tumour in your pituitary gland, ZOLADEX 10.8 mg may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness • seeing or hearing things that are not there.	

You may experience the following side effects:

Less serious side effects	What to do
• changes in blood pressure • hot flushes, sweating or feeling faint • chills • tingling in fingers or toes • swelling, soreness or itchiness of the breasts • changes in breast size • your testicles getting smaller, erectile dysfunction • vaginal dryness • mood changes, depression, personality changes • headaches • skin rashes, acne • painful joints • trouble passing urine or experience lower back pain • incontinence, needing to urinate more often • abdominal pain, abdominal swelling	**Speak to your doctor if you have any of these side effects and they worry you.**

Less serious side effects	What to do
• pain, bruising, bleeding, redness or swelling around the injection site • hair loss • weight gain	

ZOLADEX 10.8 mg lowers the amount of sex hormones in your body so your sex drive will probably be reduced.

If you have breast cancer, at the beginning of treatment a worsening of symptoms of your breast cancer such as an increase in pain and/or an increase in size of the affected tissue may occur.

Most women stop having periods while being treated with ZOLADEX 10.8 mg. Some may go through menopause while being given ZOLADEX 10.8 mg and not have periods again when the treatment is finished.

In men and in women who have not gone through menopause, ZOLADEX 10.8 mg is likely to reduce the amount of calcium in their bones leading to a loss in bone mineral density. It is known that bone mineral density loss partially recovers in the next several months following cessation of therapy. However, doctors do not know if bone mineral density loss will recover completely in every person. Discuss this with your doctor or pharmacists if you are concerned.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZOLADEX 10.8 mg contains

Active ingredient (main ingredient)	goserelin (as the acetate)
Other ingredients (inactive ingredients)	polyglactin

Do not take this medicine if you are allergic to any of these ingredients.

What ZOLADEX 10.8 mg looks like

ZOLADEX 10.8 mg (AUST R 55242) comes in a special syringe, called the SafeSystem, and a siliconised needle.

The small pellet containing ZOLADEX 10.8 mg is about the size of a grain of rice. It can be seen in the "window" half way up the syringe and is white or cream coloured.

Who distributes ZOLADEX 10.8 mg

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

This leaflet was prepared in August 2026.

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VV-RIM-06055551 v 6.0