

# ZOLADEX® 3.6 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 3.6 mg?

ZOLADEX 3.6 mg contains the active ingredient goserelin acetate. ZOLADEX 3.6 mg is used to lower the amount of sex hormones in the body. ZOLADEX 3.6 mg is used to treat breast cancer in some women before menopause, to treat endometriosis and fibroids of the uterus, to thin the lining of the womb before surgery, in combination with other drugs as part of a treatment for infertility and to treat prostate cancer in some men.

For more information, see Section [1. Why am I using ZOLADEX 3.6 mg?](#) in the full CMI.

### 2. What should I know before I use ZOLADEX 3.6 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, 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 3.6 mg?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ZOLADEX 3.6 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 3.6 mg?

A ZOLADEX 3.6 mg implant will be injected under the skin of your stomach every 28 days.

More instructions can be found in Section [4. How do I use ZOLADEX 3.6 mg?](#) in the full CMI.

### 5. What should I know while using ZOLADEX 3.6 mg?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using ZOLADEX 3.6 mg.</li><li>Make sure to keep your appointment for being given ZOLADEX 3.6 mg every four weeks.</li><li>Use barrier contraceptive methods (condom or diaphragm) while having ZOLADEX 3.6 mg treatment unless it is being used for infertility.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop being given ZOLADEX 3.6 mg unless you have discussed it with your doctor first.</li><li>Do not take oral contraceptives while being treated with ZOLADEX 3.6 mg.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how ZOLADEX 3.6 mg affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your ZOLADEX 3.6 mg in the package until you take it to the doctor or nurse to give it to you.</li><li>Keep in a cool, dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using ZOLADEX 3.6 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 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<sup>®</sup> 3.6 mg Implant SafeSystem<sup>™</sup>

Active ingredient: *goserelin acetate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOLADEX 3.6 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 3.6 mg.**

**Where to find information in this leaflet:**

- [1. Why am I using ZOLADEX 3.6 mg?](#)
- [2. What should I know before I use ZOLADEX 3.6 mg?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ZOLADEX 3.6 mg given?](#)
- [5. What should I know while using ZOLADEX 3.6 mg?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ZOLADEX 3.6 mg?

ZOLADEX 3.6 mg contains the active ingredient goserelin acetate. ZOLADEX 3.6 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).

ZOLADEX 3.6 mg is used to lower the amount of sex hormones in the body. In women it reduces the level of oestrogen. In men it reduces the level of testosterone.

ZOLADEX 3.6 mg can treat breast cancer in some women before menopause or the 'change of life'. It is not a cure for breast cancer.

ZOLADEX 3.6 mg is also used to treat endometriosis and fibroids of the uterus. These are not cancer.

ZOLADEX 3.6 mg is used to thin the lining of the womb before surgery.

ZOLADEX 3.6 mg is also used in combination with other drugs as part of a treatment for infertility.

ZOLADEX 3.6 mg can treat prostate cancer in some men. It is not a cure for prostate cancer.

### 2. What should I know before I use ZOLADEX 3.6 mg?

#### Warnings

**Do not use ZOLADEX 3.6 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
- hay fever

- difficulty breathing
- feeling faint

**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 3.6 mg.
- take any medicines for any other condition

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.**

Unless you are using ZOLADEX 3.6 mg as part of a fertility treatment do not use it while you are pregnant. It may affect the baby. We do not know if ZOLADEX 3.6 mg passes into breast milk.

It is unlikely that you can father a child or fall pregnant while using ZOLADEX 3.6 mg, unless it is for infertility treatment.

**Use a barrier contraceptive method to make sure.**

#### Children

**Do not give ZOLADEX 3.6 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.

**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 3.6 mg.**

### 4. How is ZOLADEX 3.6 mg given?

#### How much you will be given

- A ZOLADEX 3.6 mg implant will be injected under the skin of your stomach every 28 days.

- 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 four weeks.
- The ZOLADEX 3.6 mg SafeSystem incorporates a protective needle sleeve that automatically locks in place following administration of the implant to aid in the prevention of needle stick injury.

### How long to use ZOLADEX 3.6 mg

- The length of time you will use ZOLADEX 3.6 mg for depends on what illness is being treated.
- Your doctor will tell you how long you will need to be given ZOLADEX 3.6 mg.

### If you forget to be given ZOLADEX 3.6 mg

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

### If you use too much ZOLADEX 3.6 mg

The doctor or nurse giving you ZOLADEX 3.6 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 3.6 mg?

### Things you should do

**Make sure to keep your appointment for being given ZOLADEX 3.6 mg every four weeks.**

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

**Use barrier contraceptive methods (condom or diaphragm) while having ZOLADEX 3.6 mg treatment, unless it is being used for infertility.**

Tell your doctor immediately if you become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using ZOLADEX 3.6 mg.

### Things you should not do

- **Do not stop being given ZOLADEX 3.6 mg unless you have discussed it with your doctor first.**

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

- **Do not take oral contraceptives while being treated with ZOLADEX 3.6 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 3.6 mg affects you.

### Looking after your medicine

**Keep your ZOLADEX 3.6 mg in the package until you take it to the doctor or nurse to give it to you.**

If you take ZOLADEX 3.6 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
<ul style="list-style-type: none"> <li>• If you have a tumour in your pituitary gland, ZOLADEX 3.6 mg may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness.</li> </ul>	<p><b>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.</b></p>

You may experience the following side effects:

Very common (may affect more than 1 in 10 people)	What to do
<ul style="list-style-type: none"> <li>• changes in blood pressure</li> <li>• hot flushes, sweating or feeling faint</li> <li>• chills</li> <li>• tingling in fingers or toes</li> <li>• swelling, soreness or itchiness of the breasts</li> <li>• your testicles getting smaller</li> <li>• vaginal dryness</li> <li>• mood changes</li> </ul>	<p><b>Speak to your doctor if you have any of these very common side effects and they worry you.</b></p>

<b>Very common (may affect more than 1 in 10 people)</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>headache</li> </ul>	

<b>Common (may affect up to 1 in 10 people)</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>skin rashes</li> <li>painful joints</li> <li>trouble passing urine or experience lower back pain</li> </ul>	<b>Speak to your doctor if you have any of these common side effects and they worry you.</b>

ZOLADEX 3.6 mg lowers the amount of sex hormones in your body so your sex drive will probably be reduced.

Most women stop having periods while being treated with ZOLADEX 3.6 mg. Some may go through menopause while being given ZOLADEX 3.6 mg and not have periods again when the treatment is finished.

In men and in women who have not gone through the 'change of life', ZOLADEX 3.6 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 pharmacist 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](http://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 3.6 mg contains

<b>Active ingredient (main ingredient)</b>	goserelin (as the acetate)
<b>Other ingredients (inactive ingredients)</b>	polyglactin

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

### What ZOLADEX 3.6 mg looks like

ZOLADEX 3.6 mg (Aust R 24368) comes in a special syringe, called the SAFESYSTEM and a siliconised needle.

The small pellet containing ZOLADEX 3.6 mg is about the size of a grain of rice. It can be seen in the "window" halfway up the syringe and is white or cream coloured.

### Who distributes ZOLADEX 3.6 mg

AstraZeneca Pty Ltd  
 ABN 54 009 682 311  
 66 Talavera Road  
 MACQUARIE PARK NSW 2113  
 Telephone: -1800 805 342

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