

ZOLADEX[®] 10.8mg implant

SafeSystem[™]

Goserelin acetate

Consumer Medicine Information

What is in this leaflet

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

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 10.8mg 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 is for

ZOLADEX can treat prostate cancer in some men. It is not a cure for prostate cancer. ZOLADEX lowers the amount of sex hormones in the body. In men it reduces the level of testosterone.

Your doctor will have explained why you are being treated with ZOLADEX 10.8mg and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

ZOLADEX 10.8mg is not addictive.

Before you are given ZOLADEX 10.8mg

When you must not be given it

ZOLADEX 10.8mg will not normally be used in females.

There is not enough evidence to support its use in women.

ZOLADEX 10.8mg will not be given to children.

There is no information on its use in children.

It will not be used after the use by (expiry) date printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if it is used it after the expiry date.

ZOLADEX 10.8mg will not be used if the packaging is torn or shows signs of tampering.

Before you start to use it

You must tell your doctor if:

- you have allergies to any ingredients listed at the end of this leaflet or any other substances
If you have an allergic reaction, you may get a rash, hay fever, difficulty breathing or feel faint.
- you 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way ZOLADEX 10.8mg works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you given any ZOLADEX 10.8mg.

Being given ZOLADEX 10.8mg

How much you will be given

A ZOLADEX 10.8mg 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 10.8mg 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.

If you forget to be given it

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

Overdose

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

While you are using it

Things you must do

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

If you do not, your testosterone level will rise and the prostate cancer may grow more quickly.

Tell your doctor immediately if any of these things happen while you are using ZOLADEX 10.8mg

- 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

These may mean that the cancer is growing.

Things you must not do

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZOLADEX 10.8mg.

ZOLADEX 10.8mg helps most people with prostate cancer, but it may have unwanted side-effects in a few people.

It can be hard to work out whether side effects are caused by ZOLADEX 10.8mg or the disease that is being treated.

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 may have.

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

- skin rashes
- painful joints
- changes in blood pressure
- hot flushes or sweating
- chills
- tingling in fingers or toes
- swelling, soreness or itchiness of the breasts
- trouble passing urine or experience lower back pain
- your testicles getting smaller

These are all mild side effects of ZOLADEX 10.8mg.

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

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.

It is also unlikely that you can father a child while using ZOLADEX 10.8mg, but you must use your normal contraceptive method to make sure.

Your doctor will be happy to discuss these things with you if you want more information.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking ZOLADEX 10.8mg.

After using it

Storage

ZOLADEX 10.8mg will be stored by your doctor or pharmacist under the recommended conditions.

It should be kept in a cool, dry place where the temperature stays below 25°C.

Disposal

Any ZOLADEX 10.8mg which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Product description

What ZOLADEX 10.8mg looks like

ZOLADEX 10.8mg comes in a special syringe, called the SAFESYSTEM, and a siliconised needle.

The small pellet containing ZOLADEX 10.8mg 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

Ingredients

ZOLADEX 10.8mg implant contains the active ingredient goserelin 10.8mg (as the acetate) plus Polyglactin.

Distributor

AstraZeneca Pty Ltd

ABN 54 009 682 31166

Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805342

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