

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zoladex® 3.6 mg Implant goserelin

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Zoladex is and what it is used for
2. Before you are given Zoladex
3. How Zoladex will be given
4. Possible side effects
5. How to store Zoladex
6. Further information

Most of the information in this leaflet applies to both men and women.

- Where information only applies to men, it is shown by the heading **Information for men**.
- Where information only applies to women, it is shown by the heading **Information for women**.

1. What Zoladex is and what it is used for

Zoladex contains a medicine called goserelin. This belongs to a group of medicines called ‘LHRH analogues’.

Use of Zoladex by men

In men, Zoladex is used to treat prostate cancer. It works by reducing the amount of ‘testosterone’ (a hormone) that is produced by your body.

Use of Zoladex by women

In women, Zoladex is used to:

- Treat breast cancer.
- Treat a condition called ‘endometriosis’. This is where cells normally only found in the lining of the womb (uterus) are found elsewhere in your body (normally on other structures near the womb).
- Treat benign growths in the womb called ‘uterine fibroids’.
- Make the lining of the womb thinner before you have an operation on your womb.
- Help treat infertility (together with other medicines). It helps to control the release of eggs from the ovaries.

In women, Zoladex works by reducing the amount of ‘oestrogen’ (a hormone) that is produced by your body.

2. Before you are given Zoladex

Do not have Zoladex if:

- You are allergic (hypersensitive) to goserelin or any of the other ingredients of this medicine (listed in Section 6: Further information).
- You are pregnant or breast-feeding (see the section on ‘Pregnancy and breast-feeding’ below).

Do not have Zoladex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having Zoladex.

Zoladex should not be given to children.

Take special care with Zoladex

If you go into hospital, tell the medical staff that you are having Zoladex.

Check with your doctor or nurse before you have Zoladex if:

- You have high blood pressure.

There have been reports of depression in patients taking Zoladex which may be severe. If you are taking Zoladex and develop depressed mood, inform your doctor.

Information for men

Check with your doctor or nurse before you have Zoladex if:

- You have problems passing urine (water) or problems with your back.
- You have diabetes.
- You have any condition that affects the strength of your bones, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones) or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

Medicines of this type can cause a reduction in bone calcium (thinning of bones).

Information for women

Check with your doctor or nurse before you have Zoladex if:

- You have any condition that affects the strength of your bones, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones), have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

Medicines of this type can cause a reduction in bone calcium (thinning of bones). This may improve when treatment is stopped.

If you are having Zoladex for endometriosis, your doctor may reduce the thinning of the bones by giving you other medicines as well.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Pregnancy and breast-feeding

- Do not have Zoladex if you are pregnant or breast-feeding.
- Do not have Zoladex if you are trying to get pregnant (unless Zoladex is being used as part of a treatment for infertility).

- Do not use ‘the pill’ (oral contraceptives) while you are having Zoladex. Use barrier methods of contraception, such as the condom or diaphragm (cap).

Driving and using machines

Zoladex is not likely to affect you being able to drive or use any tools or machines.

3. How Zoladex will be given

- The Zoladex 3.6 mg Implant will be injected under the skin on your stomach every four weeks (28 days). This will be done by your doctor or nurse.
- It is important that you keep having Zoladex treatment, even if you are feeling well.
- Keep having this treatment until your doctor decides that it is time for you to stop.

Your next appointment

- You should be given a Zoladex injection every 28 days.
- Always remind the doctor or nurse to set up an appointment for your next injection.
- If you are given an appointment for your next injection which is earlier or later than 28 days from your last injection, tell your doctor or nurse.
- If it has been more than 28 days since your last injection, contact your doctor or nurse so that you can receive your injection as soon as possible.

Information for women

- If you are having Zoladex for uterine fibroids and you have anaemia (low levels of red blood cells or haemoglobin), your doctor may give you an iron supplement.
- The length of your treatment with Zoladex will depend on what you are having it for:
 - To treat uterine fibroids, you should only have Zoladex for up to three months.
 - To treat endometriosis, you should only have Zoladex for up to six months.
 - To make the lining of your uterus thinner before an operation on your womb, you should only have Zoladex for one or two months (four or eight weeks).

4. Possible side effects

Like all medicines, Zoladex can cause side effects, although not everybody gets them.

The following side effects can happen in men or women:

Allergic reactions:

These are rare. The symptoms can include sudden onset of:

- Rash, itching or hives on the skin.
- Swelling of the face, lips or tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

If this happens to you, **see a doctor straight away.**

Other possible side effects:

- Hot flushes and sweating.
- A reduced sex drive.
- Thinning of your bones.
- Tingling in your fingers or toes.
- Skin rashes.
- Hair loss.

- Weight gain.
- Pain in the joints.
- Changes in blood pressure.
- Pain, bruising, bleeding, redness or swelling where Zoladex is injected.
- Changes in your mood (including depression).
- Changes in your blood.
- Liver problems.
- A blood clot in your lungs causing chest pain or shortness of breath.
- Inflammation of the lungs. The symptoms may be like pneumonia (such as feeling short of breath and coughing).
- Psychiatric problems called psychotic disorders which may include hallucinations (seeing, feeling or hearing things that are not there), disordered thoughts and personality changes. This is very rare.
- The development of a tumour of the pituitary gland in your head or, if you already have a tumour in your pituitary gland, Zoladex may make the tumour bleed or collapse. These effects are very rare. Pituitary tumours can cause severe headaches, feeling or being sick, loss of eyesight and becoming unconscious.

Information for men

The following side effects can happen in men:

- Pain in your lower back or problems passing urine. If this happens, **talk to your doctor**.
- Bone pain at the beginning of treatment. If this happens, **talk to your doctor**.
- Impotence.
- Reduced heart function or heart attack.
- Swelling and tenderness of your breasts.
- Rises in blood sugar levels.

Information for women

The following side effects can happen in women:

- Changes in the amount of calcium in your blood. The signs may include feeling very sick, being sick a lot or being very thirsty. If this happens to you, **talk to your doctor** as he or she may need to do blood tests.
- Bleeding from the vagina. This is most likely to happen in the first month after starting Zoladex and should stop on its own. However, if it continues or you are uncomfortable, **talk to your doctor**.
- Headaches.
- Dryness of the vagina.
- A change in breast size.
- Small cysts (swellings) on the ovaries which can cause pain. These usually disappear without treatment.
- Some women enter the menopause early during treatment with Zoladex, and their periods do not return when Zoladex treatment is stopped.
- Acne has been reported very commonly (often within one month of starting treatment).

When Zoladex is used to treat endometriosis, uterine fibroids, infertility or for thinning of the uterus lining, the following side effects can also happen:

- Changes in body hair.
- Dry skin.
- Putting on weight.

- Raised levels of a fatty substance known as cholesterol in your blood. This would be seen in a blood test.
- Inflammation of the vagina and discharge from the vagina.
- Nervousness.
- Disturbed sleep and tiredness.
- Swelling of the feet and ankles.
- Muscle pain.
- Sudden painful muscle tightness (cramp) in your legs.
- Stomach complaints, feeling sick or being sick, diarrhoea and constipation.
- Changes to your voice.
- When used to treat uterine fibroids, a slight increase in the symptoms of fibroids, such as pain.

When Zoladex is used to treat breast cancer, the following can happen:

- Worsening of the symptoms of your breast cancer at the beginning of treatment. This can include an increase in pain or an increase in the size of the affected tissue. These effects do not usually last long and they usually go away as treatment with Zoladex is continued. However, if the symptoms continue or you are uncomfortable, **talk to your doctor**.

When Zoladex is used to treat infertility with another medicine called gonadotrophin, the following can happen:

- It can have too much of an effect on your ovaries. You may notice stomach pain, swelling of your stomach, and feeling or being sick. If this happens, **tell your doctor straight away**.

Do not be concerned by this list of possible side effects. You may not get any of them.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. How to store Zoladex

- Your doctor may give you a prescription so that you can get your medicine from the pharmacy and give it to your doctor when you see him or her again.
- Keep it in its original package and do not break the seal.
- Do not store it above 25°C.
- Keep it in a safe place where children cannot see it or reach it.
- Your medicine should not be used after the expiry date on the carton.
- If your medicine is not used, take it back to your pharmacist.

6. Further information

What Zoladex 3.6 mg Implant contains

The active substance is goserelin. Each Zoladex 3.6 mg Implant contains 3.6 mg of goserelin. The other ingredient is lactide/glycolide copolymer which is an inactive substance.

What Zoladex 3.6 mg Implant looks like and contents of the pack

Zoladex 3.6 mg Implant comes as an implant (a very small pellet) in a pre-filled syringe, ready to be used by the doctor or nurse.

Zoladex 3.6 mg Implant is produced in packs of one implant (injection).

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Zoladex 3.6 mg Implant is held by AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.
Zoladex 3.6 mg Implant is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Zoladex 3.6 mg Implant
Reference number	17901/0064

This is a service provided by the Royal National Institute of the Blind.

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