Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zoladex

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package.
- Do not use implant after the expiry date which is stated on the carton and pouch labels after 'Exp'. The expiry date refers to the last day of that month.
- If the Implant shows any sign of damage or discolouration, seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zoladex contains
The active ingredient in Zoladex is goserelin.
Each implant contains goserelin acetate equivalent to 3.6mg peptide base in a sustained release formulation. The other ingredient is lactide/glycolide co-polymer.

What Zoladex looks like and contents of the pack
Carton containing a sealed plastic pouch with instruction card attached. The pouch contains a desiccant and a pre-filled plastic SafeSystem syringe. The syringe has a white cap covering the needle and a red safety clip to protect the plunger.
One pack contains one off white implant.

Manufactured by: AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK-102NA, UK.
Or
AstraZeneca AB, Gartunavagen, SE-151 85 Sodertalje, Sweden.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Zoladex® 3.6mg Implant; PL 18799/2986 **POM**

Leaflet date: 01.08.2023

Zoladex is the registered trademark of AstraZeneca UK Limited.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package leaflet: Information for the user
ZOLADEX® 3.6mg Implant
(goserelin acetate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is ZOLADEX 3.6mg Implant but will be referred to as Zoladex throughout this leaflet.

What is in this leaflet:

1. What Zoladex is and what it is used for
2. What you need to know before you use Zoladex
3. How to use Zoladex
4. Possible side effects
5. How to store Zoladex
6. Contents of the pack and other 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. What you need to know before you use Zoladex

Do not use Zoladex:
- if you are allergic to goserelin or any of the other ingredients of this medicine (listed in section 6).
- if 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, pharmacist or nurse before having Zoladex.

Warnings and precautions

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

Talk to your doctor, pharmacist or nurse before using Zoladex:
- if you have high blood pressure.
- if you have any 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 when using 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).

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

Children

Zoladex should not be given to children.

Information for men

Talk to your doctor, pharmacist or nurse before using Zoladex:
- if you have problems passing urine (water) or problems with your back.
- if you have diabetes.

Information for women

Talk to your doctor, pharmacist or nurse before using Zoladex:
- 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.**

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

Other medicines and Zoladex

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Zoladex might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Pregnancy, breast-feeding and fertility

- 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 to use Zoladex

- Zoladex 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.
- Zoladex must be started at least 6-8 weeks before you start treatment with an aromatase inhibitor and should continue throughout treatment with the aromatase inhibitor.

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, this medicine 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.**

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.

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Hot flushes and sweating. Occasionally these side effects may continue for some time (possibly months) after stopping Zoladex.
- A reduced sex drive and impotence.
- Pain, bruising, bleeding, redness or swelling where Zoladex is injected.

Common (may affect up to 1 in 10 people)

- 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.**
- Temporary worsening of symptoms of your cancer at the beginning of treatment.
- Thinning of your bones.
- Rise in blood sugar levels.
- Tingling in your fingers or toes.
- Skin rashes.
- Hair loss.
- Weight gain.
- Pain in the joints.
- Reduced heart function or heart attack.
- Changes in blood pressure.
- Swelling and tenderness of your breasts
- Changes in your mood (including depression).

Very rare (may affect up to 1 in 10,000 people)

- 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.

Not known (frequency cannot be estimated from the available data)

- Changes in your blood.
- Liver problems including jaundice.
- 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).
- Changes in ECG (QT prolongation).
- Memory impairment

Information for men

The following side effects can happen in men:

Very common (may affect more than 1 in 10 people)

- Impotence.

Common (may affect up to 1 in 10 people)

- 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.**
- 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:

Very common (may affect more than 1 in 10 people)

- Dryness of the vagina.
- A change in breast size.
- Acne has been reported very commonly (often within one month of starting treatment).

Common (may affect up to 1 in 10 people)

- Headaches.

Rare (may affect up to 1 in 1,000 people)

- 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.

Not known (frequency cannot be estimated from the available data)

- 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.**
- A slight increase in the symptoms of fibroids, such as pain.

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.**
- 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.

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.