

Package leaflet: Information for the user
ZOLADEX® LA 10.8mg INJECTION
(goserelin)

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 LA 10.8mg INJECTION but will be referred to as Zoladex LA throughout this leaflet.

What is in this leaflet:

1. What Zoladex LA is and what it is used for
2. What you need to know before you use Zoladex LA
3. How to use Zoladex LA
4. Possible side effects
5. How to store Zoladex LA
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 LA is and what it is used for

Zoladex LA contains a medicine called goserelin. This belongs to a group of medicines called 'LHRH analogues'.

Use of Zoladex LA by men

In men, Zoladex LA 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 LA by women

In women, Zoladex LA is used to:

- Treat early and advanced breast cancer that is hormone dependent.

In women, Zoladex LA 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 LA

Do not use Zoladex LA:

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

Warnings and precautions

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

Talk to your doctor, pharmacist or nurse before using Zoladex LA:

- 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 LA.
- 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 LA 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

- 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 LA is continued. However, if the symptoms continue or you are uncomfortable, **talk to your doctor**.

Other medicines and Zoladex LA

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

3. How to use Zoladex LA

- The Zoladex LA will be injected under the skin on your stomach every 12 weeks. This will be done by your doctor or nurse.
- It is important that you keep having Zoladex LA treatment, even if you are feeling well.
- Keep having this treatment until your doctor decides that it is time for you to stop.
- The Zoladex LA 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 LA injection every 12 weeks.
- 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 12 weeks from your last injection, tell your doctor or nurse.
- If it has been more than 12 weeks since your last injection, contact your doctor or nurse so that you can receive your injection as soon as possible.

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 LA. 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 LA 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.
- Rises 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 LA 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 LA, and their periods do not return when Zoladex LA 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 LA 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.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 LA

- Keep out of the sight and reach of children.
- Zoladex LA should not be stored above 25°C. Store in the original container.
- Do not use after the expiry date printed on the carton or labelled pack.
- You may be given a prescription and asked to collect your injection from the pharmacy and keep it until you see your doctor. Keep it in the original package, do not break the seal.
- If this injection is not required, please take it back to the pharmacist for safe disposal. Only keep the injection if your doctor tells you to.
- If the injection becomes discoloured or shows any other signs of deterioration, you should consult your pharmacist who will advise you what to do.

6. Contents of the pack and other information

What Zoladex LA contains

- Your medicine is called Zoladex LA 10.8mg injection.
- It contains the active ingredient, Goserelin acetate, equivalent to 10.8mg of goserelin and also contains Lactide-glycolide co-polymer which is an inactive substance.

What Zoladex LA looks like and contents of the pack

- Zoladex LA contains a sterile, white to cream coloured, cylindrical long-acting sustained release depot.
- Zoladex LA is available as a prefilled SafeSystem single dose syringe applicator with a protective sleeve.

Manufactured by: AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, England.

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® LA 10.8mg INJECTION; PL 18799/2787

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