

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zoladex® LA 10.8mg Implant
(goserelin)

Your medicine is available using the above name but will be referred to as Zoladex LA throughout this leaflet.

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.

What is in this leaflet:

- What Zoladex LA is and what it is used for
- What you need to know before you use Zoladex LA
- How to use Zoladex LA
- Possible side effects
- How to store Zoladex LA
- 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'. Zoladex LA is a long-acting form of Zoladex LA and it is given every 12 weeks.

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 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'.

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.

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

Tell your doctor or nurse if you have or will take an anti-doping test since this medicine can produce a positive result.

Children

Zoladex LA should not be given to children.

Information for men

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

- if you have problems passing urine (water) or problems with your back.
- if you have diabetes.
- 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) or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

Medicines of this type can reduce the amount of calcium in the bones (causing thinning of bones).

Information for women

Talk to your doctor, pharmacist or nurse before you have 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).

Medicines of this type can reduce the amount of calcium in the bones (causing thinning of bones). This may improve when treatment is stopped.

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

It may take some time for your periods to return when treatment is stopped.

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 LA if you are pregnant or breast-feeding.
- Do not have Zoladex LA if you are trying to get pregnant.
- Do not use 'the pill' (oral contraceptives) while you are having Zoladex LA. 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

- 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.

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.

Information for women

- You should only have Zoladex LA for up to six months.

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 LA.
- A reduced sex drive.
- Pain, bruising, bleeding, redness or swelling where Zoladex LA is injected.

Common (may affect up to 1 in 10 people)

- Thinning of your bones.
- Tingling in your fingers or toes.
- Skin rashes.
- Hair loss.
- Weight gain.
- Pain in the joints.
- Changes in blood pressure.
- Mood changes, depression have been reported commonly.

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.
- 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).

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.
- Increased levels of sugar in your blood.

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 the uterine fibroids, such as pain.

When Zoladex LA is used to treat uterine fibroids or endometriosis, the following can happen:

- A slight increase in the symptoms of the uterine fibroids, such as pain. This does not usually last long and usually goes away as treatment with Zoladex LA 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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.
- Do not store your injection above 25°C.
- The injection should not be used after the expiry date (Exp) which is stated on the outer carton and inner packaging. The expiry date refers to the last day of that month.
- Keep your injection in its original pack and do not break the seal.
- If your doctor decides to stop your treatment, dispose of your injection in an appropriate way.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help protect the environment.
- If you have any left over, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Zoladex LA contains

Each Zoladex LA injection contains 10.8mg of goserelin as the active ingredient.

The other ingredients are a blend of high and low molecular weight lactide/glycolide copolymers.

Zoladex LA 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). In men, it will reduce levels of the male hormone, testosterone. In women, it will reduce levels of the female hormone, oestrogen.

What Zoladex LA looks like and contents of the pack

Zoladex LA comes in packs of one injection.

Manufacturer

Manufactured by: AstraZeneca UK Ltd,
Silk Road Business Park, Macclesfield, Cheshire,
SK10 2NA, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/133/1

Leaflet issue and revision date (ref): 10.02.16

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Use of Zoladex LA by women

In women, Zoladex LA is used to:

- 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'.

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.

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

Tell your doctor or nurse if you have or will take an anti-doping test since this medicine can produce a positive result.

Children

Zoladex LA should not be given to children.

Information for men

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

- if you have problems passing urine (water) or problems with your back.
- if you have diabetes.
- 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) or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

Medicines of this type can reduce the amount of calcium in the bones (causing thinning of bones).

Information for women

Talk to your doctor, pharmacist or nurse before you have 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).

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

It may take some time for your periods to return when treatment is stopped.

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 LA if you are pregnant or breast-feeding.
- Do not have Zoladex LA if you are trying to get pregnant.
- Do not use 'the pill' (oral contraceptives) while you are having Zoladex LA. 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

- 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.

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.

Information for women

- You should only have Zoladex LA for up to six months.

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 LA.
- A reduced sex drive.
- Pain, bruising, bleeding, redness or swelling where Zoladex LA is injected.

Common (may affect up to 1 in 10 people)

- Thinning of your bones.
- Tingling in your fingers or toes.
- Skin rashes.
- Hair loss.
- Weight gain.
- Pain in the joints.
- Changes in blood pressure.
- Mood changes, depression have been reported commonly.

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.
- 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).

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.
- Increased levels of sugar in your blood.

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 the uterine fibroids, such as pain.

When Zoladex LA is used to treat uterine fibroids or endometriosis, the following can happen:

- A slight increase in the symptoms of the uterine fibroids, such as pain. This does not usually last long and usually goes away as treatment with Zoladex LA 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zoladex LA

- 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 out of the sight and reach of children.
- Do not store your injection above 25°C.
- Keep your injection in its original pack and do not break the seal.
- The injection should not be used after the expiry date (Exp) which is stated on the outer carton and inner packaging. The expiry date refers to the last day of that month.
- If your doctor decides to stop your treatment, dispose of your injection in an appropriate way.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Zoladex LA contains

Each Zoladex LA injection contains 10.8mg of goserelin as the active ingredient.

The other ingredient is lactide/glycolide copolymer which is an inactive substance.

What Zoladex LA looks like and contents of the pack

Zoladex LA is a white to cream-coloured, cylindrical depot in a pre-filled syringe.

Pack size: 1 implant (injection)

Manufacturer

Manufactured by: AstraZeneca UK Ltd,
Silk Road Business Park, Macclesfield, Cheshire,
SK10 2NA, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/133/1

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