



Because the story continues...



Understanding Zoladex
Consumer Medicine Information



Zoladex[®]
goserelin

What is in this booklet

This booklet answers some of the common questions people ask about Zoladex. It does not contain all the information that is known about Zoladex.

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 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 booklet with the medicine. You may need to read it again.

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Zoladex[®] 3.6mg
goserelin

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What Zoladex 3.6 is used for

Breast cancer

Zoladex 3.6 is used to treat hormone sensitive breast cancer in some women before menopause, or the “change of life”. It is not a cure for breast cancer. It can often keep the cancer controlled for a period of time.

Endometriosis

For endometriosis, Zoladex 3.6 may be used instead of surgery. Zoladex 3.6 is not a cure for endometriosis. Zoladex 3.6 may be helpful by reducing:

- “Patches” of endometriosis tissue in the abdomen and pelvic area
- The symptoms of endometriosis, including pain

Endometriosis has no connection with any type of cancer.

Uterine fibroids

Fibroids are growths in the womb which are not cancer. For fibroids, Zoladex 3.6 may be used before surgery. Zoladex 3.6 is not a cure for uterine fibroids and may be helpful by reducing:

- The size of fibroids in or around the womb
- The symptoms of fibroids including pain

Women who are receiving Zoladex 3.6 for endometriosis or fibroids are not being treated for cancer. If you want more information about this, ask your doctor or pharmacist.

Endometrial thinning

Zoladex 3.6 can be used to thin the lining of the womb before surgery to remove the lining. This treatment is used for some types of unusual bleeding from the womb.

Infertility/assisted reproduction

Zoladex 3.6 can be used in combination with other medicines to control the release of eggs from the ovary as part of a treatment for infertility.

Your doctor may have prescribed Zoladex 3.6 for another reason. Ask your doctor if you have any questions about why Zoladex 3.6 has been prescribed for you.

Zoladex 3.6 is not addictive.

How Zoladex 3.6 works

Zoladex 3.6 is a special preparation of goserelin acetate which is designed to work in the body for 28 days after each injection.

Zoladex 3.6 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 women it will reduce the levels of the female hormone, oestrogen.

In women, female hormones make the breasts grow, prepare the womb and other sex organs for pregnancy, and increase the sex drive.

When Zoladex 3.6 lowers sex hormones, all these actions will be reduced. Due to the action of Zoladex 3.6 on hormones, Zoladex 3.6 can treat very different illnesses in both men and women.

Before you use Zoladex 3.6

You must tell your doctor

1. If you intend to become pregnant or plan to breastfeed. Do not use Zoladex 3.6 if you are pregnant, are trying to get pregnant, (except where Zoladex 3.6 is used as part of a treatment for infertility) or while breastfeeding.
2. If you have risk factors for loss of bone calcium and osteoporosis. These factors include:
 - smoking
 - having a diet low in calcium
 - having a slight build
 - having treatment with steroids for other conditions
 - poor mobility (for example, confined to a wheelchair)

When women are treated with Zoladex 3.6, the amount of calcium in their bones decreases over a period of months. Some recovery of this loss can occur when treatment has stopped. A similar condition also happens after the change of life (menopause), when the natural production of female sex hormones falls. The link between the loss of calcium while on Zoladex 3.6 and the loss of calcium after the change of life (menopause) is uncertain.

However, women who have a family history of osteoporosis and other risk factors should discuss the use of Zoladex 3.6 with their doctor before using Zoladex 3.6.

3. If you have had an allergy to any other medicines or any other substances, such as preservatives or dyes.
4. If you have had any problems passing urine or if you have had any lower back problems.
5. If you have diabetes.

If you have not told your doctor about any of the above, tell him/her before you receive any Zoladex 3.6.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

When you must not use it

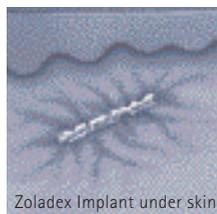
Do not use Zoladex 3.6 if:

- You are pregnant, could be pregnant or plan to get pregnant unless you are receiving it as part of a treatment for infertility or have been specially advised by your doctor.
- You are breastfeeding.
If you are breastfeeding you should discuss this with your doctor.
- You have ever had an allergic reaction to Zoladex 3.6.
- The packaging is torn or shows signs of tampering.
- The expiry date on the pack has passed. If you receive this medicine after the expiry date has passed, it may not work.

Zoladex 3.6 is not to be used in children.

Using Zoladex 3.6

Zoladex 3.6 will be given to you as an injection by your doctor or nurse. Zoladex 3.6 comes in a special syringe and needle. A small pellet containing Zoladex 3.6 is injected under the skin. The injection is often at the front of the stomach (belly), or to the side of the stomach. The small pellet containing Zoladex 3.6 is about the size of a grain of rice.



Zoladex Implant under skin

After the pellet is injected, it slowly dissolves and releases Zoladex 3.6. Each pellet takes about 4 weeks (28 days) to dissolve completely. By four weeks, almost all the Zoladex 3.6 is gone and has been used by the body. The pellet gives you a dose of Zoladex 3.6 so you are certain to get your treatment.

Each dose of Zoladex 3.6 comes in a new syringe and needle.

The number of injections with Zoladex 3.6 will depend on the illness being treated. Your doctor will tell you how long you may need to receive Zoladex 3.6.

The usual length of treatment for endometriosis or fibroids is up to 6 months. If longer courses of treatment are needed, the doctor may need to consider possible side effects related to loss of calcium in bones.

The usual length of treatment for thinning of the womb lining is either 1 injection followed by surgery four weeks later or 2 injections spaced 4 weeks apart, with surgery timed within zero to two weeks of the second injection.

If you miss a treatment

Tell your doctor if you miss your monthly treatment with Zoladex 3.6. If you have missed a dose on purpose because you do not like a side effect of the medicine, discuss this with your doctor. Talk to your doctor if you want to stop receiving Zoladex 3.6 because of side effects or for any other reason.

Overdose

Getting too much Zoladex 3.6 is unlikely, as overdose is getting more than one Zoladex 3.6 treatment in 4 weeks (28 days).

If a person got more than one dose in 4 weeks, Zoladex 3.6 would act for a bit longer. Tell your doctor if you think you have received too much Zoladex 3.6.

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre, Ph: 0800 POISON (0800 764 766), or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Zoladex 3.6, even if there are no signs of discomfort or poisoning.

While you are using Zoladex 3.6

Things you must do

Whilst receiving Zoladex 3.6 therapy, for uses other than infertility treatment, barrier methods of contraception such as the condom or diaphragm (cap) should be used. Oral forms of contraception (the "Pill") should not be taken when receiving Zoladex 3.6.

If you become pregnant while receiving Zoladex 3.6, tell your doctor immediately.

If you go into hospital, let the medical staff know you are receiving Zoladex 3.6.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are receiving Zoladex 3.6.

You should only stop receiving Zoladex 3.6 if advised to do so by your doctor.

It is unlikely that Zoladex 3.6 will affect your ability to drive a car or to operate machinery.

If you are unsure about any of these points or have further questions please tell your doctor or pharmacist.

Side effects

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Zoladex 3.6.

Zoladex 3.6 helps most people with endometriosis, fibroids, some types of unusual bleeding from the womb or breast cancer, but it may have unwanted side effects in a few people. 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 have.

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

- rare allergic reactions
- skin rashes
- painful joints
- tingling in fingers or toes
- changes in blood pressure
- thinning of bones

In the very rare case, when patients receiving Zoladex 3.6 have a tumour in their pituitary gland, Zoladex 3.6 may make the tumour bleed or collapse. This can cause severe headaches, sickness, loss of eyesight and unconsciousness.

Other side effects

Most women get signs of the change of life (menopause) while on Zoladex 3.6 such as:

- change in libido (sex drive)
- mood changes, including depression
- headache
- weight gain
- acne
- hot flushes and sweating
- a change of breast size
- a dry vagina
- hair loss

Formation of ovarian cysts may occur, which may result in pain in some women. Zoladex 3.6 will usually stop your periods. Some women will have a menstrual period in the first two weeks after the first injection of Zoladex 3.6. Rarely, some women may enter their natural menopause when being treated with Zoladex 3.6 and will not resume having periods when the treatment with Zoladex 3.6 stops.

At the beginning of treatment, a worsening of symptoms of your breast cancer, such as an increase in pain and/or an increase in the size of the affected tissue, may occur. Vaginal bleeding may occur. If you have fibroids, a slight increase in symptoms such as pain may occur. These effects are usually short-lived and discontinue on continuation of treatment. If symptoms persist or you are uncomfortable, contact your doctor. In addition, if you experience excessive nausea, vomiting or thirst, you should tell your doctor. This may indicate possible changes in the amount of calcium in your blood and your doctor may have to do certain blood tests.

If you are receiving Zoladex 3.6 for breast cancer, it can be hard to tell the difference between unwanted effects due to Zoladex 3.6 and problems due to the cancer. Discuss any changes in your condition with your doctor.

When Zoladex 3.6 is being used as part of a treatment for infertility, the sex hormones, which are given to you later, may occasionally result in over-stimulation of the ovaries. If you experience abdominal pain, abdominal swelling, nausea or vomiting after receiving these drugs for such treatment you should let your doctor know immediately.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using Zoladex 3.6.

Storage

Keep your Zoladex 3.6 in the original packet. Let your doctor or nurse break the seal. Keep in a cool, dry place where the temperature stays below 25°C. Do not store it, or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines. Keep it where children cannot reach it. A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

Once your doctor has given you the Zoladex 3.6 Implant, he or she will dispose of the syringe and needle. If your Zoladex 3.6 has passed its expiry date, ask your doctor or pharmacist how to dispose of it.

Product description

What does it look like

Zoladex 3.6 comes in a special syringe and needle. The small pellet containing Zoladex 3.6 is about the size of a grain of rice. This pellet is located inside the syringe. Zoladex 3.6 comes in packs of one injection.

Ingredients

Zoladex 3.6 contains goserelin acetate. The pellet is made of a combination of two white or cream coloured substances called polyglactins.

Medicine Classification

Zoladex is a prescription medicine.

Use strictly as directed. If symptoms continue or you experience side effects, see your doctor, pharmacist or health professional. Consult your doctor to see if Zoladex is right for you. Zoladex is a fully funded prescription medicine. Certain criteria apply. Your doctor's fee and prescription fee will still apply.

Notes

Notes

goserelin
Zoladex[®] 3.6mg

Zoladex[®] 10.8mg

goserelin

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What Zoladex 10.8 is used for

Endometriosis

For endometriosis, Zoladex 10.8 may be used instead of surgery. Zoladex 10.8 is not a cure for endometriosis. Zoladex 10.8 may be helpful by reducing:

- “Patches” of endometriosis tissue in the abdomen and pelvic area
- The symptoms of endometriosis, including pain

Endometriosis has no connection with any type of cancer.

Uterine fibroids

Fibroids are growths in the womb which are not cancer.

For fibroids, Zoladex 10.8 may be used before surgery. Zoladex 10.8 is not a cure for uterine fibroids and may be helpful by reducing:

- The size of fibroids in or around the womb
- The symptoms of fibroids including pain

Women who are receiving Zoladex 10.8 for endometriosis or fibroids are not being treated for cancer. If you want more information about this, ask your doctor or pharmacist.

Your doctor will help you understand the benefits of having Zoladex 10.8 for your particular problem. Ask your doctor for further information if he/she has prescribed this medicine for a different purpose.

Zoladex 10.8 is not addictive.

How Zoladex 10.8 works

Zoladex 10.8 is a special preparation of goserelin acetate which is designed to work in the body for 12 to 13 weeks after each injection. Most people will need one injection for each 12 to 13 weeks of treatment. Zoladex 10.8 is otherwise similar to Zoladex 3.6 mg Implant which you may have received in the past. The Zoladex 3.6 mg Implant lasts for only 28 days.

Zoladex 10.8 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 women it will reduce the levels of the female hormone, oestrogen.

In women, female hormones make the breasts grow, prepare the womb and other sex organs for pregnancy, and increase the sex drive.

When Zoladex 10.8 lowers sex hormones, all these actions will be reduced.

Due to the action of Zoladex 10.8 on hormones, Zoladex 10.8 can treat very different illnesses in both men and women.

Before you use Zoladex 10.8

You must tell your doctor:

1. If you intend to become pregnant or plan to breastfeed.
Do not use Zoladex 10.8 if you are pregnant, are trying to get pregnant, or while breastfeeding.
2. If you have risk factors for loss of bone calcium and osteoporosis.
These factors include:
 - smoking
 - having a diet low in calcium
 - having a slight build
 - poor mobility (for example, confined to a wheelchair)
 - having treatment with steroids for other conditions

When women are treated with Zoladex 10.8, the amount of calcium in their bones decreases over a period of months. Some recovery of this loss can occur when treatment is stopped. A similar condition also happens after the change of life (menopause), when the natural production of female sex hormones falls. The link between the loss of calcium while on Zoladex 10.8 and the loss of calcium after the change of life (menopause) is uncertain. However, women who have a family history of osteoporosis and other risk factors should discuss the use of Zoladex 10.8 with their doctor before using Zoladex 10.8.

3. If you have had an allergy to any other medicines or any other substances, such as preservatives or dyes.
4. If you have had any problems passing urine or if you have had any lower back problems.
5. If you have diabetes.

If you have not told your doctor about any of the above, tell him/her before you receive any Zoladex 10.8.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

When you must not use it

Do not use Zoladex 10.8 if:

- You are pregnant, could be pregnant, or plan to get pregnant unless you are receiving it as part of a treatment for infertility or have been specially advised by your doctor.
- You are breastfeeding. If you are breast feeding you should discuss this with your doctor.
- You have ever had an allergic reaction to Zoladex 10.8.
- The packaging is torn or shows signs of tampering.
- The expiry date on the pack has passed. If you receive this medicine after the expiry date has passed, it may not work.

Zoladex 10.8 is not to be used in children.

Using Zoladex 10.8

Zoladex 10.8 will be given to you as an injection by your doctor or a nurse.

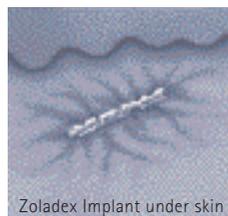
Zoladex 10.8 comes in a special syringe and needle. A small pellet containing Zoladex 10.8 is injected under the skin. The injection is often at the front of the stomach or to the side of the stomach.

The injection leaves a small pellet underneath your skin. This pellet is designed to give you a dose of Zoladex 10.8 which is released over 12 weeks (84 days). This means your injection will be given every 12 weeks. Your doctor will tell you for how long you may need to take Zoladex 10.8. It is important that you carry on receiving your Zoladex 10.8 even if feeling well unless your doctor decides it is time for the treatment to stop.

Women should only receive Zoladex 10.8 for a maximum of six months.

If you miss a treatment

You should not delay or miss your 12 weekly Zoladex 10.8. This may lead to the treatment not working.



Zoladex Implant under skin

Tell your doctor if you miss your 12-weekly treatment of Zoladex 10.8. If you have missed a dose on purpose because you do not like a side effect of the injection, discuss this with your doctor. Talk to your doctor if you do not want to receive any more Zoladex 10.8 injections because of side effects or for any other reason.

Overdose

Getting too much Zoladex 10.8 is unlikely, as overdose is getting more than one Zoladex 10.8 injection in 12 to 13 weeks. If a person received more than one injection in 12 to 13 weeks, Zoladex 10.8 would act for a bit longer. Tell your doctor if you think you have received too much Zoladex 10.8.

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre, Ph: 0800 POISON (0800 764 766), or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Zoladex 10.8, even if there are no signs of discomfort or poisoning.

While you are using Zoladex 10.8

Things you must do

If you are a woman receiving therapy with Zoladex 10.8, barrier methods of contraception such as the condom or diaphragm (cap) should be used. Oral forms of contraception (the "Pill") should not be taken when receiving Zoladex 10.8. If you become pregnant while receiving Zoladex 10.8, tell your doctor immediately.

If you go into hospital, let the medical staff know you are receiving Zoladex 10.8.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are receiving Zoladex 10.8.

You should only stop receiving Zoladex 10.8 if advised to do so by your doctor.

It is unlikely that Zoladex 10.8 will affect your ability to drive a car or to operate machinery.

If you are unsure about any of these points or have further questions please tell your doctor or pharmacist.

Side effects

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Zoladex 10.8 begins to work in the two weeks after the first injection. You should expect to notice changes in your body because your sex hormones will fall to low levels.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Zoladex 10.8.

Zoladex 10.8 helps most people with endometriosis or fibroids, but it may have unwanted side effects in a few people. 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 have.

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

- rare allergic reactions
- skin rashes
- painful joints
- tingling in fingers or toes
- changes in blood pressure
- thinning of bones

In the very rare case, when patients receiving Zoladex 10.8 have a tumour in their pituitary gland, Zoladex 10.8 may make the tumour bleed or collapse. This can cause severe headaches, sickness, loss of eyesight and unconsciousness.

Other side effects

Most women get signs of the change of life (menopause) while on Zoladex 10.8 such as:

- change in libido (sex drive)
- hot flushes and sweating
- mood changes, including depression
- a change of breast size
- headache
- a dry vagina
- weight gain
- hair loss
- acne

Formation of ovarian cysts may occur, which may result in pain in some women. Zoladex 10.8 will usually stop your periods. Some women will have a menstrual period in the first 2 weeks after the first injection of Zoladex 10.8. Rarely, some women may enter their natural menopause when being treated with Zoladex 10.8 and will not resume having periods when the treatment with Zoladex 10.8 stops. In some women, the time it takes for periods to begin again, after they stop receiving Zoladex 10.8, can be prolonged.

Vaginal bleeding may occur. If you have fibroids, a slight increase in symptoms such as pain may occur. These effects are usually short-lived and discontinue on continuation of treatment. If symptoms persist or you are uncomfortable, contact your doctor. In addition, if you experience excessive nausea, vomiting or thirst, you should tell your doctor. This may indicate possible changes in the amount of calcium in your blood and your doctor may have to do certain blood tests.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using Zoladex 10.8.

Storage

Keep your Zoladex 10.8 in the original packet. Let your doctor or nurse break the seal.

Keep in a cool, dry place where the temperature stays below 25°C. Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Once your doctor has given you the Zoladex 10.8 Implant, he or she will dispose of the syringe and needle. If your Zoladex 10.8 has passed its expiry date, ask your doctor or pharmacist how to dispose of it.

Product description

What does it look like

Zoladex 10.8 comes in a special syringe and needle. The small pellet containing Zoladex 10.8 is about the size of a grain of rice. This pellet is located inside the syringe. Zoladex 10.8 comes in packs of one injection.

Ingredients

Zoladex 10.8 contains goserelin acetate. The pellet is made of a combination of two white or cream coloured substances called polyglactins.

Medicine Classification

Zoladex is a prescription medicine.

Use strictly as directed. If symptoms continue or you experience side effects, see your doctor, pharmacist or health professional. Consult your doctor to see if Zoladex is right for you. Zoladex is a fully funded prescription medicine. Your doctor's fee and prescription fee will still apply.



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