



Goserelin

3.6 mg / **10.8** mg

Goserelin Consumer
Medicine Information

For Male Patients

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3.6 mg**

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INTRODUCTION

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

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 GOSERELIN 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.

Goserelin 3.6 mg

PROSTATE CANCER

GOSERELIN 3.6 can treat prostate cancer in some men. It is not a cure for prostate cancer, and does not work in every patient with prostate cancer.

HOW GOSERELIN 3.6 WORKS

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

GOSERELIN 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 men it will reduce levels of the male hormone, testosterone.

In men, male hormones make the testicles grow, assist an erection, and increase the sex drive.

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

BEFORE YOU USE GOSERELIN 3.6

You must tell your doctor:

1. 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)
2. If you have had an allergy to any other medicines or any other substances, such as preservatives or dyes.
3. If you have had any problems passing urine or if you have had any lower back problems.
4. If you have diabetes
5. If you have any of the following: 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 in such patients when using GOSERELIN 3.6.

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

GOSERELIN might interfere with some medicines used to treat heart rhythm problems or might increase the risk of heart rhythm problems when used with some other medicines that can cause heart rhythm abnormalities.

WHEN YOU MUST NOT USE IT

Do not use GOSERELIN 3.6 if:

- You have ever had an allergic reaction to GOSERELIN 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.

GOSERELIN 3.6 is not to be used in children.

USING GOSERELIN 3.6

GOSERELIN 3.6 will be given to you as an injection by your doctor or nurse. GOSERELIN 3.6 comes in a special syringe and needle. A small pellet containing GOSERELIN 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 GOSERELIN 3.6 is about the size of a grain of rice. After the pellet is injected, it slowly dissolves and releases GOSERELIN 3.6. Each pellet takes about 4

weeks (28 days) to dissolve completely. By four weeks, almost all the GOSERELIN 3.6 is gone and has been used by the body. The pellet gives you a dose of GOSERELIN 3.6 so you are certain to get your treatment.

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

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

IF YOU MISS A TREATMENT

Tell your doctor if you miss your monthly treatment with GOSERELIN 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 GOSERELIN 3.6 because of side effects or for any other reason.

OVERDOSE

Getting too much GOSERELIN 3.6 is unlikely, as overdose is getting more than one GOSERELIN 3.6 treatment in 4 weeks (28 days). If a person got more than one dose in 4 weeks, GOSERELIN 3.6 would act for a bit longer. Tell your doctor if you think you have received too much GOSERELIN 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 GOSERELIN 3.6, even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING GOSERELIN 3.6

THINGS YOU MUST DO

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

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

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

It is unlikely that GOSERELIN 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 GOSERELIN 3.6.

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 GOSERELIN 3.6 have a tumour in their pituitary gland, GOSERELIN 3.6 may make the tumour bleed or collapse. This can cause severe headaches, sickness, loss of eyesight and unconsciousness.

OTHER SIDE EFFECTS

Sometimes side effects may be symptoms of the prostate cancer you are being treated for. Therefore you should always tell your doctor if you notice any possible side effect.

For most men, their sex life will be poor. You may have a reduced sex drive. You may not be able to get an erection or father a child. However, GOSERELIN 3.6 is not a contraceptive for men and should never be used that way. You may get hot flushes and sweating. Some men may get swollen or tender breasts. The testicles may become smaller.

When you first start receiving GOSERELIN 3.6 you may feel some pain in your bones. If this happens, tell your doctor and you may be given something for this.

Very occasionally you may have trouble passing urine or experience lower back pain. If this happens, tell your doctor and you may be given something for this.

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 GOSERELIN 3.6.

STORAGE

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

PRODUCT DESCRIPTION**WHAT DOES IT LOOK LIKE?**

GOSERELIN 3.6 comes in a special syringe and needle. The small pellet containing GOSERELIN 3.6 is about the size of a grain of rice.

This pellet is located inside the syringe. GOSERELIN 3.6 comes in packs of one injection.

INGREDIENTS

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

MEDICINE CLASSIFICATION

GOSERELIN 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 GOSERELIN is right for you. GOSERELIN is a fully funded prescription medicine. Certain criteria apply. Your doctor's fee and prescription fee will still apply.

Goserelin 10.8 mg

PROSTATE CANCER

GOSERELIN 10.8 can treat prostate cancer in some men. It is not a cure for prostate cancer, and does not work in every patient with prostate cancer.

HOW GOSERELIN 10.8 WORKS

GOSERELIN 10.8 is a special preparation of goserelin acetate which is designed to work in the body for 12 weeks after each injection. Most people will need one injection for each 12 weeks of treatment. GOSERELIN

10.8 is otherwise similar to GOSERELIN 3.6 mg Implant which you may have received in the past. The GOSERELIN 3.6 mg Implant lasts for only 28 days.

GOSERELIN 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 men it will reduce levels of the male hormone, testosterone.

In men, male hormones make the testicles grow, assist an erection, and increase the sex drive.

When GOSERELIN 10.8 lowers sex hormones, all these actions will be reduced. Due to the action of GOSERELIN 10.8 on hormones, GOSERELIN 10.8 can treat very different illnesses in both men and women.

BEFORE YOU USE GOSERELIN 10.8

You must tell your doctor:

1. 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)
2. If you have had an allergy to any other medicines or any other substances, such as preservatives or dyes.
3. If you have had any problems passing urine or if you have had any lower back problems.
4. If you have diabetes
5. If you have any of the following: 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 in such patients when using GOSERELIN 3.6.

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

GOSERELIN might interfere with some medicines used to treat heart rhythm problems or might increase the risk of heart rhythm problems when used with some other medicines that can cause heart rhythm abnormalities.

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 GOSERELIN 10.8 if:

- You have ever had an allergic reaction to GOSERELIN 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

GOSERELIN 10.8 is not to be used in children.

USING GOSERELIN 10.8

GOSERELIN 10.8 will be given to you as an injection by your doctor or a nurse. GOSERELIN 10.8 comes in a special syringe and needle. A small pellet containing GOSERELIN

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 GOSERELIN

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 GOSERELIN 10.8. It is important that you carry on receiving your GOSERELIN 10.8 even if feeling well unless your doctor decides it is time for the treatment to stop.

If you miss a treatment

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

Tell your doctor if you miss your 12-weekly treatment of GOSERELIN 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 GOSERELIN 10.8 injections because of side effects or for any other reason.

OVERDOSE

Getting too much GOSERELIN 10.8 is unlikely, as overdose is getting more than one GOSERELIN 10.8 injection in 12 weeks (84 days). If a person received more than one injection in 12 weeks, GOSERELIN 10.8 would act for a bit longer. Tell your doctor if you think you have received too much GOSERELIN 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 GOSERELIN 10.8, even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING GOSERELIN 10.8

THINGS YOU MUST DO

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

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

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

It is unlikely that GOSERELIN 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.

GOSERELIN 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 GOSERELIN 10.8.

GOSERELIN 10.8 helps most people with prostate 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 GOSERELIN 10.8 have a tumour in their pituitary gland, GOSERELIN 10.8 may make the tumour bleed or collapse. This can cause severe headaches, sickness, loss of eyesight and unconsciousness.

OTHER SIDE EFFECTS

Sometimes side effects may be symptoms of the prostate cancer you are being treated for. Therefore you should always tell your doctor if you notice any possible side effect.

For most men, their sex life will be poor during treatment with GOSERELIN 10.8. You may have a low sex drive. You may not be able to get an erection or father a child. However, GOSERELIN 10.8 is not a contraceptive for men and should never be used in that way. You may get hot flushes and sweating. Some men may get swollen or tender breasts. The testicles may become smaller.

When you first start receiving GOSERELIN 10.8 you may feel some pain in your bones. If this happens, tell your doctor and you may be given something for this.

Very occasionally you may have trouble passing urine or experience lower back pain. If this happens, tell your doctor and you may be given something for this.

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 GOSERELIN 10.8.

STORAGE

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

PRODUCT DESCRIPTION

WHAT DOES IT LOOKS LIKE

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

INGREDIENTS

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MEDICINE CLASSIFICATION

GOSERELIN 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 GOSERELIN is right for you. GOSERELIN is a fully funded prescription medicine. Your doctor's fee and prescription fee will still apply.



Goserelin-Teva, 3.6mg and 10.8mg, injectable implants are Prescription Medicines for the treatment of Prostate Cancer in some men. It is not a cure for prostate cancer and does not work in every patient with prostate cancer. Goserelin-Teva has risks and benefits. 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 Goserelin-Teva is right for you. Goserelin-Teva is fully funded. Normal Doctor charges apply. Marketed by: Teva Pharma (New Zealand) Limited PO Box 128 244, Remuera Auckland 1541 Telephone: 0800 800 097. Further information is available on request.

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