



Goserelin

3.6 mg / **10.8** mg

Goserelin Consumer
Medicine Information

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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

WHAT IS GOSERELIN 3.6 MG USED FOR?

BREAST CANCER

GOSERELIN 3.6 is used to treat hormone sensitive breast cancer in some patients 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, GOSERELIN 3.6 may be used instead of surgery. GOSERELIN 3.6 is not a cure for endometriosis. GOSERELIN 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, GOSERELIN 3.6 may be used before surgery. GOSERELIN 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

Patients who are receiving GOSERELIN 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

GOSERELIN 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

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

GOSERELIN 3.6 is not addictive.

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 patients it will reduce the levels of the hormone, oestrogen.

In patients, hormones make the breasts grow, prepare the womb and other sex organs for pregnancy, 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 intend to become pregnant or plan to breastfeed. Do not use GOSERELIN 3.6 if you are pregnant, are trying to get pregnant, (except where GOSERELIN 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 patients are treated with GOSERELIN 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 sex hormones falls. The link between the loss of calcium while on GOSERELIN 3.6 and the loss of calcium after the change of life (menopause) is uncertain.

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

WHEN YOU MUST NOT USE IT

Do not use GOSERELIN 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 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.

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 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**

Whilst receiving GOSERELIN 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 GOSERELIN 3.6.

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

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.

GOSERELIN 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 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

Most patients get signs of the change of life (menopause) while on GOSERELIN 3.6 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 patients. GOSERELIN 3.6 will usually stop your periods. Some patients will have a menstrual period in the first two weeks after the first injection of GOSERELIN 3.6. Rarely, some patients may enter their natural menopause when being treated with GOSERELIN 3.6 and will not resume having periods when the treatment with GOSERELIN 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 GOSERELIN 3.6 for breast cancer, it can be hard to tell the difference between unwanted effects due to GOSERELIN 3.6 and problems due to the cancer. Discuss any changes in your condition with your doctor.

When GOSERELIN 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 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.

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

ENDOMETRIOSIS

For endometriosis, GOSERELIN 10.8 may be used instead of surgery. GOSERELIN 10.8 is not a cure for endometriosis. GOSERELIN 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, GOSERELIN 10.8 may be used before surgery. GOSERELIN 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

Patients who are receiving GOSERELIN 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 GOSERELIN 10.8 for your particular problem. Ask your doctor for further information if he/ she has prescribed this medicine for a different purpose.

GOSERELIN 10.8 is not addictive.

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 to 13 weeks after each injection. Most people will need one injection for each 12 to 13 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 patients it will reduce the levels of the hormone, oestrogen.

In patients, hormones make the breasts grow, prepare the womb and other sex organs for pregnancy, 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 intend to become pregnant or plan to breastfeed. Do not use GOSERELIN 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 patients are treated with GOSERELIN 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 sex hormones falls. The link between the loss of calcium while on GOSERELIN 10.8 and the loss of calcium after the change of life (menopause) is uncertain.

However, patients who have a family history of osteoporosis and other risk factors should discuss the use of GOSERELIN 10.8 with their doctor before using GOSERELIN 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 GOSERELIN 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 GOSERELIN 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 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.

Patients should only receive GOSERELIN 10.8 for a maximum of six months. If you miss a treatment

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 to 13 weeks. If a person received more than one injection in 12 to 13 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 are a patient receiving therapy with GOSERELIN 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 GOSERELIN 10.8. If you become pregnant while receiving GOSERELIN 10.8, tell your doctor immediately.

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 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 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

Most patients get signs of the change of life (menopause) while on GOSERELIN 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 patients.

GOSERELIN 10.8 will usually stop your periods. Some patients will have a menstrual period in the first 2 weeks after the first injection of GOSERELIN 10.8. Rarely, some patients may enter their natural menopause when being treated with GOSERELIN 10.8 and will not resume having periods when the treatment with GOSERELIN 10.8 stops. In some patients, the time it takes for periods to begin again, after they stop receiving GOSERELIN 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 GOSERELIN 10.8.

STORAGE

Keep your GOSERELIN 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 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

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

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 Breast Cancer, Endometriosis, Uterine fibroids, Endometrial thinning and Infertility/assisted reproduction in some patients. It is not a cure for and does not work in every patient. 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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