Version 4, 02/2016

SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

/.../ 10.8 mg implant, in a pre-filled syringe

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One implant contains 10.8 mg goserelin (as goserelin acetate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Implant, in a pre-filled syringe.

White to off-white cylindrical rods (approximate dimensions: diameter 1.5 mm, length 20 mm, mass 44 mg), embedded in biodegradable polymer matrix.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

/.../ is indicated (see also section 5.1):
- In the treatment of metastatic prostate cancer where goserelin has demonstrated comparable survival benefits to surgical castrations (see section 5.1).
- In the treatment of locally advanced prostate cancer, as an alternative to surgical castration where goserelin has demonstrated comparable survival benefits to an anti-androgen (see section 5.1).
- As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer where goserelin has demonstrated improved disease-free survival and overall survival (see section 5.1).
- As neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer where goserelin has demonstrated improved disease-free survival (see section 5.1).
- As adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression where goserelin has demonstrated improved disease-free survival (see section 5.1).

4.2 Posology and method of administration

Posology

Adult males (including older people)
One depot of /.../ injected subcutaneously into the anterior abdominal wall every 12 weeks.

Paediatric population
/.../ is not indicated for use in children.

Special populations
Patients with renal impairment
No dosage adjustment is necessary for patients with renal impairment.

Patients with hepatic impairment
No dosage adjustment for patients with hepatic impairment.

Method of administration
/.../ is indicated for subcutaneous use. For correct administration of /.../, see instructions on the carton box.

Caution is needed when administering /…/ into anterior abdominal wall due to the proximity of underlying inferior epigastric artery and its branches.

Extra care to be given to patients with a low BMI or who are receiving anticoagulation medication (see section 4.4).

Care should be taken to ensure injection is given subcutaneously, using the technique described on the pouch. Do not penetrate into a blood vessel, muscle or peritoneum.

In the event of the need to surgically remove a /…/ implant, it may be localised by ultrasound.

For special precautions for disposal and other handling see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Goserelin is not indicated for use in females, since there is insufficient evidence of reliable suppression of serum estradiol. For female patients requiring treatment with goserelin, refer to the prescribing information for /.../ 3.6 mg.

There is no data on removal or dissolution of the implant.

There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as goserelin. Patients should be informed accordingly and treated as appropriate if symptoms occur.

The use of goserelin in patients at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and the patients monitored closely during the first month of therapy. If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted.

Androgen deprivation therapy may prolong the QT interval.

In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval (see section 4.5) physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating /.../.

Injection site injury has been reported with goserelin, including events of pain, haematoma, haemorrhage and vascular injury. Monitor affected patients for signs or symptoms of abdominal haemorrhage. In very rare cases, administration error resulted in vascular injury and haemorrhagic shock requiring blood transfusions and surgical intervention. Extra care should be taken when administering goserelin to patients with a low BMI and/or receiving full anticoagulation medications (see section 4.2).

Consideration should be given to the initial use of an anti-androgen (e.g. cyproterone acetate 300 mg daily for three days before, and three weeks after commencement of /.../) at the start of LHRH analogue therapy since this has been reported to prevent the possible sequelae of the initial rise in serum testosterone.

The use of LHRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an LHRH agonist may reduce bone mineral loss. Particular caution is necessary in patients with additional risk factors for osteoporosis (e.g. chronic alcohol abusers, smokers, long-term therapy with anticonvulsants or corticosteroids, family history of osteoporosis).

Patients with known depression and patients with hypertension should be monitored carefully.

Myocardial infarction and cardiac failure were observed in a pharmaco-epidemiology study of LHRH agonists used in the treatment of prostate cancer. The risk appears to be increased when used in combination with anti-androgens.

Reduction in glucose tolerance has been observed in men receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in patients with pre-existing diabetes mellitus. Thus, monitoring of blood glucose levels should be considered.

Treatment with goserelin may lead to positive reactions in anti-doping tests.

Paediatric population
Goserelin is not indicated for use in children, as safety and efficacy have not been established in this patient group.

4.5 Interaction with other medicinal products and other forms of interaction

Since androgen deprivation treatment may prolong the QT interval, the concomitant use of /.../ with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated (see section 4.4).

4.6 Fertility, pregnancy and lactation

Goserelin is not indicated for use in females

4.7 Effects on ability to drive and use machines

Goserelin has no or negligible influence on the ability to drive and use machinery.

4.8 Undesirable effects

The following frequency categories for adverse drug reactions (ADRs) were calculated based on reports from goserelin clinical trials and post-marketing sources. The most commonly observed adverse reactions include hot flushes, sweating and injection site reactions.

The following convention has been used for classification of frequency: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000) and Not known (cannot be estimated from the available data).

Table: Goserelin adverse drug reactions presented by MedDRA System Organ Class

MedDRA SOC	***Frequency***	***Adverse reaction***
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Very rare	Pituitary tumour
Immune system disorders	Uncommon	Drug hypersensitivity

MedDRA SOC	*Frequency*	*Adverse reaction*
	Rare	Anaphylactic reaction
Endocrine disorders	Very rare	Pituitary haemorrhage
Metabolism and nutrition disorders	Common	Glucose tolerance impaired[a]
Psychiatric disorders	Very common	Libido decreased[b]
	Common	Mood changes, depression
	Very rare	Psychotic disorder
Nervous system disorders	Common	Paraesthesia Spinal cord compression
Cardiac disorders	Common	Cardiac failure[f], myocardial infarction[f]
	Not known	QT prolongation (see sections 4.4 and 4.5)
Vascular disorders	Very common	Hot flush[b]
	Common	Blood pressure abnormal[c]
Skin and subcutaneous tissue disorders	Very common	Hyperhidrosis[b]
	Common	Rash[d]
	Not known	Alopecia[g]
Musculoskeletal and connective tissue disorders	Common	Bone pain[e]
	Uncommon	Arthralgia
Renal and urinary disorders	Uncommon	Ureteric obstruction
Reproductive system and breast disorders	Very common	Erectile dysfunction
	Common	Gynaecomastia
	Uncommon	Breast tenderness
General disorders and administration site conditions	Common	Injection site reaction
Investigations	Common	Bone density decreased (see section 4.4), weight increased

[a] A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes mellitus.
[b] These are pharmacological effects which seldom require withdrawal of therapy. Hyperhidrosis and hot flushes may continue after stopping goserelin.
[c] These may manifest as hypotension or hypertension, have been occasionally observed in patients administered goserelin. The changes are usually transient, resolving either during continued therapy or after cessation of therapy with goserelin. Rarely, such changes have been sufficient to require medical intervention, including withdrawal of treatment from goserelin.
[d] These are generally mild, often regressing without discontinuation of therapy.
[e] Initially, prostate cancer patients may experience a temporary increase in bone pain, which can be managed symptomatically.
[f] Observed in a pharmaco-epidemiology study of LHRH agonists used in the treatment of prostate cancer. The risk appears to be increased when used in combination with anti-androgens.
[g] Particularly loss of body hair, an expected effect of lowered androgen levels.

Post-marketing experience
A small number of cases of changes in blood count, hepatic dysfunction, pulmonary embolism and interstitial pneumonia have been reported in connection with goserelin.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

There is not much experience of overdose in humans. In cases where goserelin has been given before the planned time of administration, or when a bigger dose of goserelin than originally planned has been given, no clinically significant undesirable effects have been observed. Animal tests suggest that no effect other than the intended therapeutic effects on sex hormone concentrations and on the reproductive tract will be evident with higher doses of goserelin. In case of overdosage, the condition should be managed symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gonadotropin releasing hormone analogues, ATC code: L02AE03.

Goserelin (D-Ser(But)6Azgly10 LHRH) is a synthetic analogue of naturally occurring luteinising-hormone releasing hormone (LHRH). On chronic administration goserelin results in inhibition of pituitary luteinising hormone secretion leading to a fall in serum testosterone concentrations in males. Initially, goserelin like other LHRH agonists transiently increases serum testosterone concentrations.

In men by around 21 days after the first depot injection, testosterone concentrations have fallen to within the castrate range and remain suppressed with treatment every 12 weeks.

In the management of patients with metastatic prostate cancer, goserelin has been shown in comparative clinical trials to give similar survival outcomes to those obtained with surgical castrations.

In a combined analysis of 2 randomised controlled trials comparing bicalutamide 150 mg monotherapy versus castration (predominantly in the form of goserelin), there was no significant difference in overall survival between bicalutamide-treated patients and castration-treated patients (hazard ratio = 1.05 [CI 0.81 to 1.36]) with locally advanced prostate cancer. However, equivalence of the two treatments could not be concluded statistically.

In comparative trials, goserelin has been shown to improve disease-free survival and overall survival when used as an adjuvant therapy to radiotherapy in patients with high-risk localised (T1-T2 and PSA of at least 10 ng/ml or a Gleason score of at least 7), or locally advanced (T3-T4) prostate cancer. The optimum duration of adjuvant therapy has not been established; a comparative trial has shown that 3 years of adjuvant goserelin gives significant survival improvement compared with radiotherapy alone. Neo-adjuvant goserelin prior to radiotherapy has been shown to improve disease-free survival in patients with high risk localised or locally advanced prostate cancer.

After prostatectomy, in patients found to have extra-prostatic tumour spread, adjuvant goserelin may improve disease-free survival periods, but there is no significant survival improvement unless patients have evidence of nodal involvement at time of surgery. Patients with pathologically staged locally advanced disease should have additional risk factors such as PSA of at least 10 ng/ml or a Gleason score of at least 7 before adjuvant goserelin should be considered. There is no evidence of improved clinical outcomes with use of neo-adjuvant goserelin before radical prostatectomy.

5.2 Pharmacokinetic properties

Administration of goserelin every 12 weeks ensures that exposure to goserelin is maintained with no clinically significant accumulation. Goserelin is poorly protein bound and has a serum elimination half-life of two to four hours in subjects with normal renal function. The half-life is increased in patients with impaired renal function. For the compound given in a 10.8 mg depot formulation every 12 weeks this change will not lead to any accumulation. Hence, no change in dosing is necessary in these patients. There is no significant change in pharmacokinetics in patients with hepatic failure.

5.3 Preclinical safety data

Following long-term repeated dosing with goserelin, an increased incidence of benign pituitary tumours has been observed in male rats. Whilst this finding is similar to that previously noted in this species following surgical castration, any relevance to humans has not been established.

In mice, long-term repeated dosing with multiples of the human dose produced histological changes in some regions of the digestive system. This is manifested by pancreatic islet cell hyperplasia and a benign proliferative condition in the pyloric region of the stomach, also reported as a spontaneous lesion in this species. The clinical relevance of these findings is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poly(D,L-lactide)
Poly(D,L-lactide-co-glycolide) 75:25

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Prior to first opening: 4 years.

After first opening: The product should be used immediately after opening of the pouch.

6.4 Special precautions for storage

Do not store above 30°C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Single dose syringe applicator consisting of three main parts: the body with the implant holder unit, a mandrin and a needle unit. The applicator is packed together with a desiccant capsule in a pouch composed of three laminated layers (from the outside): PETP-film, aluminium layer, PE-film. The pouches are subsequently packed into a carton box.

/.../ is available in carton boxes of 1, 2 or 3 pouches with implant, in a pre-filled syringe.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use as directed by the prescriber. Use only if pouch is undamaged. Dispose of the syringe in an approved sharps collector.

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

<[To be completed nationally]>

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

/.../ 10.8 mg implant, in a pre-filled syringe

goserelin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One implant contains 10.8 mg goserelin (as goserelin acetate).

3. LIST OF EXCIPIENTS

Contains Poly(D,L-lactide) and Poly(D,L-lactide-co-glycolide) 75:25

4. PHARMACEUTICAL FORM AND CONTENTS

Implant, in a pre-filled syringe
1 pouch with implant, in a pre-filled syringe
2 pouches with implant, in a pre-filled syringe
3 pouches with implant, in a pre-filled syringe

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Use only if pouch is undamaged.
Use immediately after opening pouch.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot:

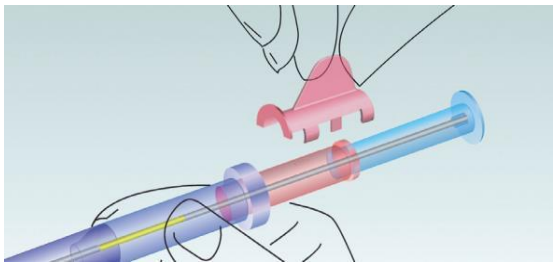
14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

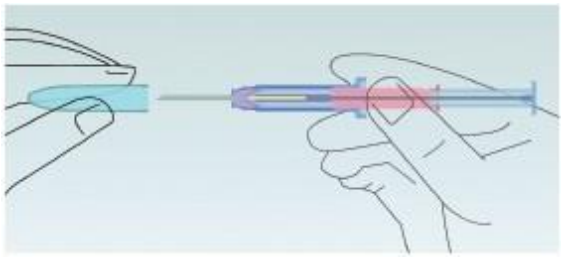
Instructions on use

Image1



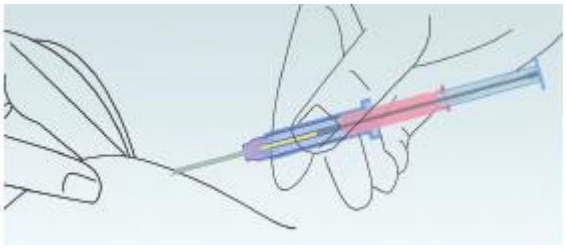
Remove the applicator from the sterile pack.
Check whether the implant is in the intended position in the applicator.
Remove the safety ring (image 1).

Image 2



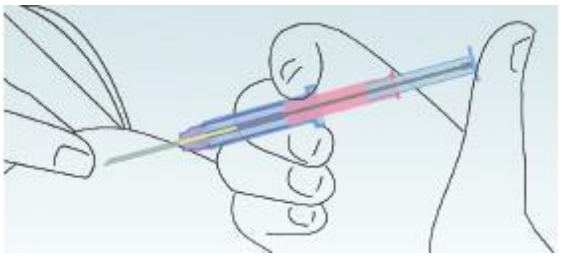
Grip the applicator on the syringe barrel and remove the protective cover (image 2).

Image 3



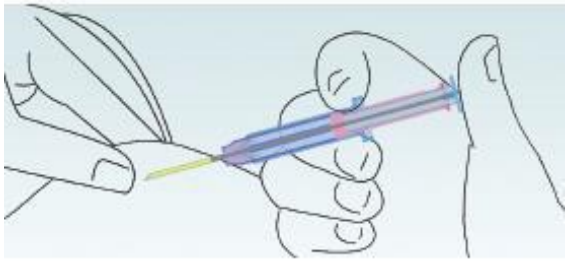
Press the skin of the patient together while you are comprising the syringe barrel and insert the needle obliquely (almost parallel to the skin).
Insert the needle so far into the subcutaneous tissue (not in muscle or into the abdominal cavity) of the anterior abdominal wall under the umbilical line, until the syringe barrel touches the patient's skin.
This contact with the skin must remain during the entire application process! (image 3).

Image 4



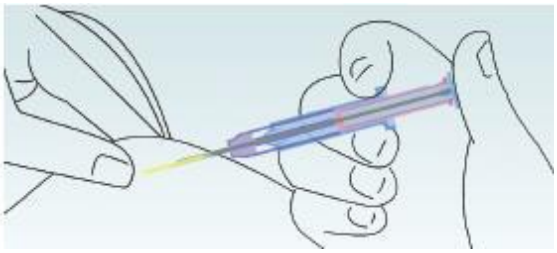
Press the syringe plunger down. The implant is transported to the needle tip.
Do not pull the syringe back in any case. During the application the syringe barrel has to touch the skin of the patient! (image 4).

Image 5



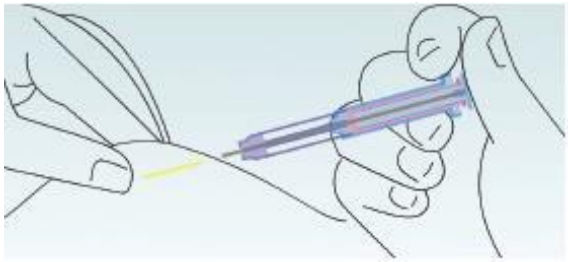
When the plunger is stopped, the needle retraction is unlocked automatically.

Image 6



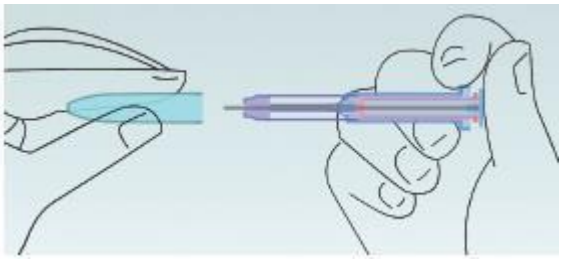
The needle is retracted from the tissue into the syringe barrel. **The syringe barrel must remain in contact with the patient's skin**. Normally the plunger movement forward and needle retraction are carried out in one smooth motion (image 6).

Image 7



The application process is completed. The needle has been fully retracted into the barrel of the syringe.
The supernatant mandrel protects against injury at the needle tip (image 7).

Image 8



Replace the protective cover again.
Dispose the syringe in the container provided (image 8).

16. INFORMATION IN BRAILLE

/.../ 10.8 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE APPLICATOR

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

/.../ 10.8 mg implant, in a pre-filled syringe

goserelin
SC

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

POUCH LABEL

1. NAME OF THE MEDICINAL PRODUCT

/.../ 10.8 mg implant, in a pre-filled syringe

Goserelin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

{Name}

3. EXPIRY DATE

4. BATCH NUMBER

5. OTHER

PACKAGE LEAFLET

Package leaflet: Information for the user

/.../ 10.8 mg implant, in a pre-filled syringe

goserelin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What /…/ is and what it is used for

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

/.../ is used to treat prostate cancer. It works by reducing the amount of 'testosterone' (a hormone) that is produced by your body. /.../ is a long-acting form of /.../ and it is given every 12 weeks.

2. What you need to know before you are given /…/

You should not be given /…/
- if you are allergic to goserelin or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman.

Do not have /.../ if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having /.../.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using /…/:
- if you have problems passing urine (water) or problems with your back;
- if you have diabetes;
- if you have high blood pressure;
- 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);
- 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 /.../.

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

Medicines of this type can cause a reduction in bone calcium (thinning of bones).
If you go into hospital, tell the medical staff that you are having /.../.

Tell your doctor if you have or will take an anti-doping test since treatment with /…/ can produce a positive result.

Children
/.../ should not be given to children.

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

/.../ might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide and ibutilide) 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).

Driving and using machines
/.../ is not likely to affect you being able to drive or use any tools or machines.

3. How /…/ will be given to you

The /.../ 10.8 mg implant 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 /.../ 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 /.../ injection every 12 weeks.
- Always remind the doctor or nurse to set up an appointment for your next injection.
- If you are given an appointment for your next injection which is earlier or later than 12 weeks from your last injection, tell your doctor or nurse.
- If it has been more than 12 weeks since your last injection, contact your doctor or nurse so that you can receive your injection as soon as possible.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 /…/. 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 goserelin.
- A reduced sex drive and 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**.
- Thinning of your bones.
- Rises in blood sugar levels.
- Tingling in your fingers or toes.
- Skin rashes.
- Weight gain.
- Pain, bruising, bleeding, redness or swelling where goserelin is injected.
- Reduced heart function or heart attack.
- Changes in blood pressure.
- Swelling and tenderness of your breasts.
- Changes in your mood (including depression).

Uncommon (may affect up to 1 in 100 people):
- Pain in the joints.

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, goserelin 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):
- Hair loss.
- 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).

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting

system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /…/

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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP:". The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep it in its original package in order to protect from moisture and do not break the seal.

After first opening: The product should be used immediately after opening of the pouch.

6. Contents of the pack and other information

What /.../ contains

- The active substance is goserelin.
  One implant contains 10.8 mg goserelin (as goserelin acetate).
- The other ingredients are Poly(D,L-lactide) and Poly(D,L-lactide-co-glycolide) 75:25.

What /.../ looks like and contents of the pack

White to off-white cylindrical rods (approximate dimensions: diameter 1.5 mm, length 20 mm, mass 44 mg), embedded in biodegradable polymer matrix.

Single dose syringe applicator consisting of three main parts: the body with the implant holder unit, a mandrin and a needle unit. The applicator is packed together with a desiccant capsule in a pouch composed of three laminated layers (from the outside): PETP-film, aluminium layer, PE-film. The pouches are subsequently packed into a carton box.

/.../ is available in carton boxes of 1, 2 or 3 pouches with implant, in a pre-filled syringe.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>