

## PATIENT INFORMATION LEAFLET

# Zoladex<sup>®</sup> 3.6mg

goserelin

**Please read this leaflet carefully. This leaflet only gives a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.**

### WHAT YOU SHOULD KNOW ABOUT YOUR MEDICINE

The name of your medicine is 'Zoladex'. The active ingredient is goserelin. Each 'Zoladex' injection contains 3.6 mg of goserelin. It also contains lactide-glycolide copolymer which is an inactive substance.

'Zoladex' is produced in packs of one injection.

Goserelin is one of a group of medicines called LHRH analogues. In men, it reduces the production of testosterone in the body and, in women, it reduces the production of oestrogen in the body.

The Marketing Authorisation for 'Zoladex' is held by

**AstraZeneca UK Limited,**

600 Capability Green, Luton, LU1 3LU, UK.

'Zoladex' is manufactured by

**AstraZeneca UK Limited,**

Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

**PLEASE READ THE SECTION OF THIS LEAFLET WHICH APPLIES TO YOU – EITHER MALE OR FEMALE.**

### USE OF 'ZOLADEX' IN MEN

'Zoladex' is used to treat prostate cancer.

### BEFORE RECEIVING YOUR MEDICINE

'Zoladex' should not be given if you have previously had an allergic reaction to 'Zoladex' or to this type of medicine.

'Zoladex' should not be given to children.

Tell your doctor if you are taking other medicines, including those you may have bought.

Have you had any problems passing urine or have you had any problems with your back? If so, tell your doctor.

If you go into hospital, tell the medical staff that you are receiving 'Zoladex'.

Your injection is unlikely to affect your ability to drive a car or to operate machinery.

### RECEIVING YOUR MEDICINE

'Zoladex' is given as an injection under the skin on your stomach every 28 days by your doctor or a nurse. It is important that you keep on receiving your treatment, even if you are feeling well, unless your doctor decides that it is time for the treatment to stop.

Your Zoladex injection should be given every four weeks (28 days). 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 either earlier or later than 28 days from your last injection, tell the doctor or nurse. If it has been more than 28 days since your last injection, contact the doctor or nurse so that you can receive your injection as soon as possible.

### AFTER RECEIVING YOUR MEDICINE

As with all medicines, undesirable events can sometimes be experienced with 'Zoladex'. These may include hot flushes and sweating, a reduced sex drive, thinning of bones and sometimes breast swelling and tenderness. In some men, there can be bone pain, lower back pain or possibly some problems with passing urine at the beginning of treatment. If this happens, tell your doctor about it. Other possible undesirable events are tingling in fingers or toes, skin rashes, rare allergic reactions, pain in the joints, or changes in blood pressure.

If you have a tumour in your pituitary gland, 'Zoladex' may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness.

Occasionally mild bruising may occur where 'Zoladex' is injected.

Do not be alarmed by this list of possible events. You may not have any of them.

If you get any other undesirable events or if you think your medicine is causing any problems, tell your doctor or pharmacist.

### STORING YOUR MEDICINE

You may be given a prescription and asked to get your medicine from the pharmacy and keep it until you see the doctor again. Keep it in its original package and don't break the seal. Store it below 25°C and keep it in a safe place where children cannot see it or reach it.

Your medicine should not be used after the expiry date on the carton.

If your medicine is not used, take it back to your pharmacist.

### FURTHER INFORMATION

This leaflet does not contain the complete information on 'Zoladex'. If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

The information applies only to 'Zoladex'.

## USE OF 'ZOLADEX' IN WOMEN

'Zoladex' can be used to treat breast cancer, endometriosis (a condition in which cells normally only found lining the womb are found elsewhere, most commonly they are found on other organs near the womb), uterine fibroids (benign growths which occur in the womb), to make the lining of the uterus thinner before having an operation or (in combination with other drugs) to control the release of eggs from the ovary as part of a treatment for infertility.

### BEFORE RECEIVING YOUR MEDICINE

'Zoladex' should not be given if you have previously had an allergic reaction to 'Zoladex' or to this type of medicine.

'Zoladex' should not be given if you are pregnant, trying to become pregnant (except where 'Zoladex' is used as part of a treatment for infertility) or if you are breast feeding.

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

'Zoladex' should not be given to children.

Medicines of this type can cause a small loss of calcium from the bones (thinning of bones). Some recovery of this loss can occur when treatment is stopped.

If you are suffering from any disease which affects the strength of your bones please make sure that your doctor is aware of this. If you are being treated for endometriosis, your doctor may reduce the thinning of the bones caused by 'Zoladex' by giving you additional treatment.

Tell your doctor if you are taking any other medicines, including those you may have bought.

If you go into hospital, tell the medical staff that you are receiving 'Zoladex'.

Your injection is unlikely to affect your ability to drive a car or to operate machinery.

### RECEIVING YOUR MEDICINE

'Zoladex' is given as an injection under the skin on your stomach by your doctor or a nurse. It is important that you keep on receiving your treatment, even if you are feeling well, unless your doctor decides that it is time for the treatment to stop.

If you are receiving 'Zoladex' for uterine fibroids and are anaemic, 'Zoladex' may be given with an iron supplement.

If you are receiving 'Zoladex' for endometriosis you should only receive treatment for a maximum of six months. Treatment for uterine fibroids should be restricted to three months. If the treatment is to make the lining of the uterus thinner it should be for four or eight weeks only.

Your 'Zoladex' injection should be given every four weeks (28 days). 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 either earlier or later than 28 days from your last injection, tell the doctor or nurse. If it has been more than 28 days since your last injection, contact the doctor or nurse so that you can receive your injection as soon as possible.

### AFTER RECEIVING YOUR MEDICINE

As with all medicines, undesirable events can sometimes be experienced with 'Zoladex'. These may include hot flushes and sweating, reduced sex drive, headaches, mood changes including depression, vaginal dryness and change in breast size. Other possible undesirable events are tingling in fingers or toes, skin rashes, rare allergic reactions, pain in the joints, changes in blood pressure, or thinning of bones.

Occasionally some women enter the menopause early, so when 'Zoladex' treatment is stopped menstruation will not start again.

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 it does, it is usually during the first month following treatment. 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 have a tumour in your pituitary gland, 'Zoladex' may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness.

Occasionally mild bruising may occur where 'Zoladex' is injected.

When 'Zoladex' is used as part of a treatment for infertility, the sex hormones, which are given to you later, may very occasionally result in overstimulation 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.

Small cysts (swellings) on the ovaries can sometimes occur following the use of 'Zoladex' and may cause pain for some women. They usually disappear without treatment.

Do not be alarmed by this list of possible events. You may not have any of them.

If you get any other undesirable events or if you think your medicine is causing any problems, tell your doctor or pharmacist.

### STORING YOUR MEDICINE

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Leaflet prepared: September 2001

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