PRESCRIBING INFORMATION

ZOLADEX® 3.6mg Implant and ZOLADEX® LA 10.8mg Implant
(goserelin acetate equivalent to 3.6mg and 10.8mg goserelin). Single dose Safe System™ syringe applicator with protective sleeve.

Consult Summary of Product Characteristics before prescribing.

**Indication:** 3.6mg & 10.8mg: Treatment of metastatic prostate cancer where Zoladex has demonstrated comparable survival benefits to surgical castrations. Treatment of locally advanced prostate cancer, as an alternative to surgical castration where Zoladex has demonstrated comparable survival benefits to an anti-androgen. As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer where Zoladex has demonstrated improved disease-free survival and overall survival. As neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer where Zoladex has demonstrated improved disease-free survival. 3.6mg only: Advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation. As an alternative to chemotherapy in the standard of care for pre/perimenopausal women with oestrogen receptor (ER) positive early breast cancer. In the management of endometriosis, Zoladex alleviates symptoms, including pain, and reduces the size and number of endometrial lesions. Indicated for the prethinning of the uterine endometrium prior to endometrial ablation or resection. Uterine fibroids: In conjunction with iron therapy in the haematological improvement of anaemic patients with fibroids prior to surgery. Assisted reproduction: Pituitary downregulation in preparation for superovulation.

**Presentation:** Implant, in pre-filled syringe. 3.6mg or 10.8mg goserelin (as goserelin acetate).

**Dosage and administration:** 3.6mg in adults: One depot injected subcutaneously into the anterior abdominal wall, every 28 days (see SmPC for important additional detail). The instruction card has to be read prior to administration. No dosage adjustment is necessary for patients with renal or hepatic impairment or in the elderly. **Endometriosis:** Treatment for 6 months only. Repeat courses should not be given due to concern about loss of bone mineral density. **Endometrial thinning:** 4 or 8 weeks treatment. **Uterine fibroids:** Treat for up to 3 months before surgery. **Assisted reproduction:** Pituitary gland downregulation usually takes between 7 and 21 days. 10.8mg in adult males (including the elderly): One depot injected subcutaneously into the anterior abdominal wall every 12 weeks (see SmPC for important additional detail). The instruction card has to be read prior to administration. No dosage adjustment is necessary for patients with renal or hepatic impairment. 3.6mg & 10.8mg: Zoladex is not indicated in children.

**Contraindications:** Hypersensitivity to active substance or any of the excipients. 3.6mg only: Pregnancy and lactation.

**Warnings and precautions:** Zoladex 10.8mg is not indicated for use in females as there is insufficient evidence of reliable suppression of serum estradiol. 3.6mg & 10.8mg (males & females): Increased risk of incident depression (which may be severe) in patients...
undergoing treatment with GnRH agonists. Patients should be informed accordingly and treated as appropriate if symptoms occur. Androgen deprivation therapy may prolong QT interval. Assess benefit/risk ratio including potential for Torsade de pointes prior to initiation in patients with history of, or risk factors for QT prolongation and patients receiving concomitant medicinal products that may prolong QT interval. Injection site injury reported. Monitor affected patients for symptoms of abdominal haemorrhage. In very rare cases, administration error resulted in vascular injury and haemorrhagic shock. Extra caution when administering to patients with a low BMI and/or those receiving full anticoagulation medications. **3.6mg & 10.8mg (males):** Consider carefully use in men at particular risk of developing ureteric obstruction or spinal cord compression and monitor closely during first month of therapy. Consideration should be given to the initial use of an anti-androgen at the start of LHRH analogue therapy since this has been reported to prevent the possible sequelae of the initial rise in serum testosterone. LHRH agonists may cause reduction in bone mineral density, particular caution is necessary in patients with additional risk factors for osteoporosis. Treatment with Zoladex may lead to positive reactions in anti-doping tests. Patients with known depression and patients with hypertension should be monitored carefully. May cause reduction in glucose tolerance which may manifest as diabetes or loss of glycaemic control in patients with pre-existing diabetes mellitus. Consider monitoring blood glucose levels. Myocardial infarction and cardiac failure risk may increase when used in combination with anti-androgens. **3.6mg only:** **Loss of bone mineral density:** Current data suggest that recovery of bone loss occurs after cessation of therapy. For breast cancer, may cause reduction in bone mineral density. Preliminary data suggest use in combination with tamoxifen may reduce bone mineral loss. In benign indications, bone mineral density reductions are likely. For the treatment of endometriosis, addition of HRT has shown to reduce bone mineral density loss and vasomotor symptoms. Treatment should only be initiated for patients with established osteoporosis or with risk factors for osteoporosis if benefits outweigh the risks. **Withdrawal bleeding:** Vaginal bleeding during early treatment (<1 month). If bleeding continues, investigate cause. Cervical resistance may be increased. **Assisted Reproduction:** For experienced, specialist use only. Use with caution in patients with polycystic ovarian syndrome. Ovarian hyperstimulation syndrome (OHSS), associated with use in combination with gonadotrophin reported. Fertile women should use non-hormonal contraceptive methods during treatment, and until reset of menstruation following discontinuation of treatment.

**Drug interactions:** Evaluate carefully concomitant use with medicinal products known to prolong 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.

**Pregnancy and lactation:** 3.6mg only: Do not use during pregnancy; not recommended during breast-feeding.

**Undesirable events:** Consult SmPC for full list of side effects. Very common: Males & females: Libido decreased, hot flush, hyperhidrosis, injection site reaction. Males: Erectile dysfunction. Females: Acne, vulvovaginal dryness, breast enlargement. Common: Males: Glucose tolerance impaired, mood changes, depression, paraesthesia, spinal cord compression, cardiac failure, myocardial infarction, blood pressure abnormal, rash, bone pain, gynaecomastia, injection site reaction, bone density decreased, weight increase. Females: Mood changes, depression, paraesthesia, headache, blood pressure abnormal, rash, alopecia, arthralgia, injection site reaction, tumour flare, tumour pain (on
initiation of treatment), bone density decreased, weight increase. **Serious**: Males & females: Hypersensitivity, anaphylactic reaction, pituitary tumour, pituitary haemorrhage, psychotic disorder, QT prolongation. **Males**: Ureteric obstruction. **Females**: Hypercalcaemia. **Post-Marketing Experience**: Hepatic dysfunction, pulmonary embolism, interstitial pneumonia.

**Legal category**: POM.

**Marketing Authorisation Number(s)**: Zoladex 3.6mg Implant PL 17901/0064; Zoladex LA 10.8mg Implant PL 17901/0065.

**Presentation & Basic NHS cost/depot**: Zoladex 3.6mg Implant: £70; Zoladex LA 10.8mg Implant: £235.

**Marketing Authorisation Holder and further information is available from**: AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AstraZeneca on 0800 783 0033.

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