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. As adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression where Zoladex has demonstrated improved disease-free survival. **3.6mg only:** Management of oestrogen receptor (ER) positive early and advanced breast cancer in pre and peri menopausal women. 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. **10.8mg only:** Management of oestrogen-receptor (ER) positive early and advanced breast cancer in pre and peri menopausal women.

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

Dosage and Administration: **The instruction card has to be read prior to administration.** **3.6mg in adults:** One depot injected subcutaneously into the anterior abdominal wall, every 28 days (see SmPC for important additional detail). 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:** One depot injected subcutaneously into the anterior abdominal wall every 12 weeks (see SmPC for important additional detail). No dosage adjustment is necessary for patients with renal or hepatic impairment or in the elderly. **3.6mg & 10.8mg: Breast cancer:** Consult the prescribing information of coadministered medicinal products, such as aromatase inhibitors, tamoxifen, CDK4/6 inhibitors, when administered in combination with goserelin. Treatment with LHRH agonists must be initiated at least 6-8 weeks before starting aromatase inhibitor treatment. The treatment should be administered on schedule and without interruption throughout aromatase inhibitor treatment. Prior to starting aromatase inhibitor treatment, the ovarian suppression should be confirmed by low blood concentrations of FSH and oestradiol. Women receiving chemotherapy, Zoladex LA should be commenced after completion of chemotherapy, once pre-menopausal status has been

confirmed. Irrespective of menstrual status, premenopausal status should be confirmed following chemotherapy and before commencement of Zoladex LA, in order to avoid unnecessary treatment with LHRH agonists in the event of a chemotherapy-induced menopause. Zoladex is not indicated in children.

Contraindications: Hypersensitivity to active substance or any of the excipients. Pregnancy and lactation.

Warnings and Precautions: **3.6mg & 10.8mg (males & females):** There is no data on removal or dissolution of the implant. 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. Patients with known depression or history of depression should be monitored carefully. 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 signs and 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. Treatment with Zoladex may lead to positive reactions in anti-doping tests. Patients with hypertension and patients with risk factors for diabetes with treatment initiated should be monitored carefully. **3.6mg & 10.8mg (males):** Consider careful use in men at particular risk of developing ureteric obstruction or spinal cord compression and monitor closely during first month of therapy. If spinal cord compression or renal impairment due to uretic obstruction are present or develop, appropriate treatment of these complications should be instituted. 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. 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 & 10.8mg (females): Breast cancer:** After commencement of goserelin, confirm adequate ovarian suppression in pre- and peri-menopausal women before initiating aromatase inhibitor therapy. **Reduced 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. **Tumour flare:** Initially, breast cancer patients may experience a temporary increase in signs and symptoms, which can be managed symptomatically. **Hypercalcemia:** Rarely, breast cancer patients with metastases have developed hypercalcaemia on initiation of therapy. If hypercalcaemia symptoms occur (e.g. thirst), hypercalcaemia should be excluded. **Withdrawal bleeding:** Vaginal bleeding during early treatment (< 1 month). If bleeding continues, investigate cause. Fertile women should use non-hormonal contraceptive methods during treatment, and until reset of menstruation following discontinuation of treatment. **3.6mg (females) only: Loss of bone mineral density:** 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. 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.

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: Do not use during pregnancy; not recommended during breast-feeding. Prior to treatment, potentially fertile women should be examined carefully to exclude pregnancy. Non-hormonal methods of contraception should be used during treatment until menses resume.

Undesirable Events: Consult SmPC for full list of side effects. Very common: Males & females: Libido decreased, hot flush, hyperhidrosis. **Males:** Erectile dysfunction. **Females:** Acne, vulvovaginal dryness, breast enlargement, injection site reaction. **Common: Males & females:** Mood changes, depression, paraesthesia, blood pressure abnormal, rash**,** bone density decreased, weight increase. **Males:** Glucose tolerance impaired, spinal cord compression, cardiac failure, myocardial infarction, bone pain, gynaecomastia, injection site reaction. **Females:** Headache, alopecia, arthralgia, tumour flare, tumour pain (on initiation of treatment). **Other Serious: Males & females**: Hypersensitivity, anaphylactic reaction, pituitary tumour, pituitary haemorrhage, psychotic disorder, QT prolongation, anaemia, leucopenia, thrombocytopenia, hepatic dysfunction and jaundice, pulmonary embolism, interstitial lung disease. Memory Impairment. **Males:** Ureteric obstruction, tumour flare (on initiation of treatment). **Females:** Hypercalcaemia.

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: Zoladex 3.6mg Implant: £70; Zoladex LA 10.8mg Implant: £235.

Business Responsible for Sale and Supply / Further Information: AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London N1C 4AG**,** UK.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com or by calling 0800 783 0033.