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Barnsley Hospital NHS Foundation Trust | South West Yorkshire Partnership NHS Foundation Trust | South Yorkshire Integrated Care Board

Goserelin 3.6mg implant (Zoladex®)

Adjuvant treatment of breast cancer in premenopausal and perimenopausal women

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (https://www.medicinescomplete.com/#/) and the SPC (https://www.medicines.org.uk/emc/) remain authoritative.

Background Information	Goserelin 3.6mg implant can be used as adjuvant treatment of advanced breast cancer in women who are pre-menopausal or peri-menopausal suitable for hormone manipulation.
BNF therapeutic class[1]	8.3.4.2 Gonadorelin analogues and gonadotrophin-releasing hormone antagonists
Indication[2]	Advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation; in the management of oestrogen receptor (ER) positive early and advanced breast cancer in pre and peri menopausal women.
Dosage and administration[2]	Adults Goserelin (Zoladex®) 3.6mg implant (in pre-filled syringe) should be administered by subcutaneous injection into the anterior abdominal wall every 28 days. The specialist should specify the length of treatment with Zoladex® 3.6mg implant.
Cautions and Contraindication[2]	**Contraindications** • Known severe hypersensitivity to the active substance or to any of the excipients of this product. • Pregnancy and lactation **Cautions** 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. Androgen deprivation therapy may prolong the QT interval. The SPC states that the frequency of QT prolongation with Zoladex® 3.6mg implant is not known. 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 physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating goserelin. Also refer to the monitoring section below. Injection site injury has been reported, 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. The use of goserelin may cause reduction in bone mineral density. In the majority of women, currently available data suggest that recovery of bone loss occurs after cessation of therapy. 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. The specialist should assess the risk of osteoporosis (refer to monitoring section below).

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	During early treatment with goserelin some women may experience vaginal bleeding of variable duration and intensity. If vaginal bleeding occurs it is usually in the first month after starting treatment. Such bleeding probably represents oestrogen withdrawal bleeding and is expected to stop spontaneously. If bleeding continues, the reason should be investigated. The use of goserelin may cause an increase in cervical resistance and care should be taken when dilating the cervix. Fertile women should use non-hormonal contraceptive methods during treatment with goserelin and until reset of menstruation following discontinuation of treatment with goserelin. Patients with known depression and patients with hypertension should be monitored carefully. Treatment with Zoladex® may lead to positive reactions in anti-doping tests.
Adverse Drug Reactions[2]	The most commonly observed adverse reactions include hot flushes, sweating and injection site reactions. Other adverse events which have been reported include hypersensitivity reactions, arthralgia, skin rashes, acne, alopecia, vulvovaginal dryness, breast enlargement, headache (occasionally severe), paraesthesia, tumour flare and tumour pain (on initiation of treatment), mood changes, decreased libido, depression, weight gain, decrease in bone density and changes in blood pressure. (These changes are usually transient and can be Hypotension or Hypertension). For full list, see SPC at www.medicines.org.uk
Pregnancy and Breast feeding[2]	Zoladex® is contra-indicated in pregnancy and breast feeding.
Monitoring[2]	Patients with known depression and patients with hypertension should be monitored carefully (see cautions above). In the case of patients with known depression, the patient should be counselled by the initiating specialist, and this should be documented in the patient's notes. Blood pressure should be measured before initiation of Zoladex® and if the patient is found to have hypertension, the primary care clinician should be advised in writing so that the patient can be managed appropriately. Since androgen deprivation treatment may prolong the QT interval, the specialist should consider carrying out a baseline ECG prior to the initiation of Zoladex®. The specialist should also consider repeating the ECG post initiation of Zoladex®. The specialist will request the baseline DEXA scan where required. Once the patient is discharged, the primary care clinician should request any further DEXA scans if recommended after the baseline scan.
Interactions[2]	Since androgen deprivation treatment may prolong QT interval, the concomitant use of Zoladex® 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) antiarrythmic products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated.

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References

1. British National Formulary. Available at: https://bnf.nice.org.uk/drug/goserelin.html <Accessed 09/01/2023>
2. Summary of Product Characteristics Zoladex® 3.6mg implant. Available at: www.medicines.org.uk/emc/product/1543/smpc <Accessed 20/09/2023>

Development Process

This guideline was developed following an AMBER-G (Amber with guidance) classification status of Goserelin for the adjuvant treatment of breast cancer in pre and peri-menopausal women, by the Barnsley Area Prescribing Committee. This guideline was ratified at the Area Prescribing Committee on 8th November 2023.