For the use of a Cancer specialist/Institutions/Hospitals only

Abbreviated Prescribing Information

Goserelin acetate implant Injection BP 3.6mg

Zoladex® 3.6 mg

COMPOSITION:

Each pre-filled injection contains: Goserelin acetate equivalent to 3.6 mg peptide base in a sustained release implant. It is supplied as a single dose SafeSystem™ syringe applicator (with a protective sleeve in a sealed pouch) to be administered every 4 weeks.

CLINICAL PHARMACOLOGY:

Zoladex (D-Ser(Bu^t)^6 $Azgly^{10}$ LHRH) is a synthetic analogue of naturally occurring LHRH. On chronic administration Zoladex results in inhibition of pituitary LH secretion leading to a fall in serum estrogen and testosterone concentrations in women and men, respectively. Initially, there may be a transient increase in serum sex steroid hormone concentration. By around 21 days after the first depot injection, estrogen or testosterone concentrations fall to within castrate range and remain suppressed with continuous treatment every 28 days. This inhibition leads to breast or prostate tumour regression and symptomatic improvement in the majority of patients. The bioavailability of Zoladex is almost complete. Administration of a depot every four weeks ensures that effective concentrations are maintained with no tissue accumulation. Zoladex 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 monthly in a depot formulation, this change will have minimal effect. Hence, no change in dosing is necessary in these patients. There is no significant change in pharmacokinetics in patients with hepatic failure. INDICATIONS: Prostate Cancer: Zoladex is indicated in the management of prostate cancer suitable for hormonal manipulation. Breast cancer: Zoladex is indicated in the management of breast cancer in premenopausal and perimenopausal women suitable for hormonal manipulation. Endometriosis: In the management of endometriosis,

INDICATIONS AND USAGE

Zoladex alleviates symptoms, including pain and reduces the size and number of endometrial lesions. Uterine fibroids: In conjunction with iron therapy in the hematological improvement of anaemic patients with fibroids prior to surgery. Endometrial thinning: Zoladex is indicated for the pre-thinning of the uterine endometrium prior to endometrial ablation or resection Assisted reproduction: Pituitary down regulation in preparation for superovulation.

DOSAGE AND ADMINISTRATION

Adults: One 3.6 mg depot of Zoladex injected subcutaneously into the anterior abdominal wall, every 28 days. No dosage adjustment is necessary for patients with renal impairment. No dosage adjustment is necessary for patients with hepatic impairment. No dosage adjustment is necessary in the elderly.

Children: Zoladex is not indicated for use in children.

CONTRA-INDICATIONS

Hypersensitivity to Zoladex or other LHRH analogues. Pregnancy and Lactation.

PRECAUTIONS

Children: Zoladex is not indicated for use in children, as safety and efficacy have not been established in this group of patients. Males: Use in patients at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and patients monitored during first month of therapy. Females: Exclude pregnancy before treatment. Non-hormonal contraception should be employed during therapy. Loss of bone mineral density, which may recover on cessation of therapy. Caution in women with known metabolic bone disease. Increase in cervical resistance, requiring care if dilating the cervix. Currently, there are no clinical data on the effects of treating benign endometriosis conditions with Zoladex for periods in excess of six months. An increase in benign pituitary tumours has been observed in male rats following long-term repeated dosing. (Relevance to man not established). Pancreatic islet cell hyperplasia and a benign proliferative condition in the pyloric region of the stomach observed in mice following long term repeated dosing with human dose (relevance to man is unknown). There is no evidence that Zoladex results in impairment of ability to drive or operate machinery.

PREGNANCY AND LACTATION

Although reproductive toxicology in animals gave no evidence of teratogenic potential, Zoladex should not be used in pregnancy, as there is a theoretical risk of abortion or foetal abnormality if LHRH agonists are used during pregnancy. Potentially fertile women should be examined carefully before treatment to exclude pregnancy. Non-hormonal methods of contraception should be employed during therapy. The use of Zoladex during breast-feeding is not recommended.

SIDE EFFECTS

Rarely, hypersensitivity, skin rashes, generally mild. Arthralgia. Changes in blood pressure. Occasional mild bruising at injection site. Males: Hot flushes, decrease in potency, infrequently breast swelling and tenderness. Temporary increase in bone pain, isolated case of ureteric obstruction and spinal cord compression have been recorded. Females: Hot flushes and sweating, change in libido, headaches, mood changes including depression, change in breast size. Temporary increase in signs and symptoms. Degeneration of fibroids.

LIST OF EXCIPIENTS: Lactide/glycolide copolymer.

PRESENTATION: A sterile depot containing goserelin 3.6mg (as acetate) as a SafeSystem™.

PRECAUTION FOR STORAGE: Store below 25°C

Zoladex is a Trade Mark of the AstraZeneca Group of Companies.

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For more information refer full prescribing information as per Version 4 dated 28/07/2016