Zoladex® LA (Goserelin acetate Implant Injection BP 10.8mg)

Abbreviated Prescribing Information

COMPOSITION:

Each prefilled injection contains Goserelin acetate (equivalent to 10.8 mg goserelin).

THERAPEUTIC INDICATIONS

Treatm ZOLADEX LA is indicated in the management of prostate cancer suitable for hormonal manipulation.

POSOLOGY AND METHOD OF ADMINISTRATION

Adult Males (including the elderly): One Implant of ZOLADEX LA injected subcutaneously into the anterior abdominal wall, every 12 weeks.

CONTRAINDICATIONS

Known severe hypersensitivity to the active substance or to any of the excipients of this product interaction. (Please refer to full prescribing information).

WARNINGS & PRECAUTIONS

ZOLADEX LA is not indicated for use in females, since there is insufficient evidence of reliable suppression of serum estradiol. Particular caution is necessary in patients with additional risk factors for osteoporosis. Patients with known depression and patients with hypertension should be monitored carefully.

PREGNANCY AND LACTATION

Zoladex LA is not indicated for use in females.

UNDESIRABLE EFFECTS

The most frequently reported adverse reactions were decreased libido,hot flush,erectile dysfunction, and hyperhidrosis. Please refer to full prescribing information or detailed assessment of adverse events.

INTERACTIONS

Since androgen deprivation treatment may prolong the QT interval, the concomitant use of Zoladex LA with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA or class III antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated

PHARMACOLOGICAL PROPERTIES

Mechanism of action

Zoladex is a synthetic analogue of naturally occurring luteinising-hormone releasing hormone (LHRH). On chronic administration Zoladex LA results in inhibition of pituitary luteinising hormone secretion leading to a fall in serum testosterone concentrations in males.

Pharmacokinetic properties

Administration of ZOLADEX LA every 12 weeks ensures that exposure to goserelin is maintained with no clinically significant 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. Hence, no change in dosing is necessary in these patients. There is no significant change in pharmacokinetics in patients with hepatic failure.

PHARMACEUTICAL PARTICULARS

Excipients

A blend of high and low molecular weight lactide/glycolide copolymers.

Shelf life

3 years

Storage

Do not store above 30°C and protect from moisture

Presentation

'ZOLADEX' LA is presented as a sterile, white to cream coloured cylindrical Implant in which goserelin acetate (equivalent to 10.8 mg of goserelin) is dispersed in a biodegradable matrix of lactide-glycolide co-polymer. It is supplied as a single dose SafeSystem™ syringe applicator with a protective sleeve in a sealed pouch which contains a desiccant.

For Further Information Contact:
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For more information, refer full prescribing information Version 4 dated 28th July 2016