

• SIDE-EFFECTS

- ▶ **Common or very common** Alopecia · arthralgia · bone pain · breast abnormalities · depression · glucose tolerance impaired · gynaecomastia · headache · heart failure · hot flush · hyperhidrosis · mood altered · myocardial infarction · neoplasm complications · paraesthesia · sexual dysfunction · skin reactions · spinal cord compression · vulvovaginal disorders · weight increased
- ▶ **Uncommon** Hypercalcaemia (in women) · ureteral obstruction
- ▶ **Rare or very rare** Ovarian and fallopian tube disorders · pituitary haemorrhage · pituitary tumour · psychotic disorder
- ▶ **Frequency not known** Abdominal cramps · body hair change · constipation · diarrhoea · fatigue · hepatic function abnormal · interstitial pneumonia · muscle complaints · nausea · nervousness · peripheral oedema (when used for gynaecological conditions) · premature menopause · pulmonary embolism · QT interval prolongation · sleep disorder · uterine leiomyoma degeneration · voice alteration · vomiting · vulvovaginal infection · withdrawal bleed

SIDE-EFFECTS, FURTHER INFORMATION Tumour flare can occur when androgen deprivation therapy is initiated.

- **CONCEPTION AND CONTRACEPTION** Non-hormonal, barrier methods of contraception should be used during entire treatment period. Pregnancy should be excluded before treatment, the first injection should be given during menstruation or shortly afterwards or use barrier contraception for 1 month beforehand.

- **PREGNANCY** Avoid.

- **BREAST FEEDING** Avoid.

- **MONITORING REQUIREMENTS** Men at risk of tumour 'flare' should be monitored closely during the first month of therapy for prostate cancer.

- **DIRECTIONS FOR ADMINISTRATION** Rotate injection site to prevent atrophy and nodule formation.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Implant

- ▶ **Zoladex** (AstraZeneca UK Ltd)

Goserelin (as Goserelin acetate) 3.6 mg Zoladex 3.6mg implant SafeSystem pre-filled syringes | 1 pre-filled disposable injection [PoM] £70.00 DT = £70.00

- ▶ **Zoladex LA** (AstraZeneca UK Ltd)

Goserelin (as Goserelin acetate) 10.8 mg Zoladex LA 10.8mg implant SafeSystem pre-filled syringes | 1 pre-filled disposable injection [PoM] £235.00 DT = £235.00

Leuprorelin acetate

26-May-2020

- **DRUG ACTION** Administration of gonadorelin analogues produces an initial phase of stimulation; continued administration is followed by down-regulation of gonadotrophin-releasing hormone receptors, thereby reducing the release of gonadotrophins (follicle stimulating hormone and luteinising hormone) which in turn leads to inhibition of androgen and oestrogen production.

• INDICATIONS AND DOSE

PROSTAP 3 DCS[®]

Prostate cancer (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION
- ▶ Adult: 11.25 mg every 3 months

Endometriosis (specialist use only)

- ▶ BY INTRAMUSCULAR INJECTION
- ▶ Adult: 11.25 mg every 3 months for maximum duration of 6 months (not to be repeated), to be started during first 5 days of menstrual cycle

Pre- and perimenopausal breast cancer (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION
- ▶ Adult: 11.25 mg every 3 months, for further information on use with adjuvant treatments, consult product literature

PROSTAP SR DCS[®]

Prostate cancer (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION, OR BY INTRAMUSCULAR INJECTION
- ▶ Adult: 3.75 mg every month

Endometriosis (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION, OR BY INTRAMUSCULAR INJECTION
- ▶ Adult: 3.75 mg every month for maximum duration of 6 months (not to be repeated), to be started during first 5 days of menstrual cycle

Endometrial thinning before intra-uterine surgery (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION, OR BY INTRAMUSCULAR INJECTION
- ▶ Adult: 3.75 mg for 1 dose, dose to be given as a single dose between day 3 and 5 of menstrual cycle, 5–6 weeks before surgery

Reduction of size of uterine fibroids and of associated bleeding before surgery (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION, OR BY INTRAMUSCULAR INJECTION
- ▶ Adult: 3.75 mg every month usually for 3–4 months (maximum 6 months)

Preservation of ovarian function (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION, OR BY INTRAMUSCULAR INJECTION
- ▶ Adult: Initially 3.75 mg as a single dose 2 weeks before starting chemotherapy, followed by 3.75 mg every month for the duration of chemotherapy treatment

Pre- and perimenopausal breast cancer (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION
- ▶ Adult: 3.75 mg every month, for further information on use with adjuvant treatments, consult product literature

STALADEX[®] 10.72MG

Prostate cancer (specialist use only)

- ▶ BY SUBCUTANEOUS INJECTION
- ▶ Adult: 10.72 mg every 3 months, to be administered under the skin of the abdomen

• CONTRA-INDICATIONS

GENERAL CONTRA-INDICATIONS Undiagnosed vaginal bleeding

SPECIFIC CONTRA-INDICATIONS

- ▶ When used for endometriosis Use longer than 6 months (do not repeat)
- **CAUTIONS** Diabetes · family history of osteoporosis · patients with metabolic bone disease (decrease in bone mineral density can occur) · risk of spinal cord compression in men with prostate cancer · risk of ureteric obstruction in men with prostate cancer

• SIDE-EFFECTS

- ▶ **Common or very common** Appetite decreased · arthralgia · bone pain · breast abnormalities · depression · dizziness · fatigue · gynaecomastia · headache · hepatic disorders · hot flush · hyperhidrosis · injection site necrosis · insomnia · mood altered · muscle weakness · nausea · paraesthesia · peripheral oedema · sexual dysfunction · testicular atrophy · vulvovaginal dryness · weight change
- ▶ **Uncommon** Alopecia · diarrhoea · fever · myalgia · palpitations · visual impairment · vomiting