PRESCRIBING INFORMATION
PROSTAP* SR DCS/ PROSTAP* 3 DCS
Leuprorelin Acetate Depot Injection 3.75mg/11.25mg

Presentation: Powder and solvent for prolonged-release suspension for injection in pre-filled Dual Chamber Syringe (DCS). Prostap SR DCS Powder: contains 3.75mg of leuprorelin acetate, equivalent to 3.57mg base. Prostap 3 DCS Powder: contains 11.25mg of leuprorelin acetate, equivalent to 10.72mg base. **Indications:** Prostap SR DCS/Prostap 3 DCS: as an adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression; as an adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer; locally advanced prostate cancer, as an alternative to surgical castration; metastatic prostate cancer; management of endometriosis including pain relief and reduction of endometriotic lesions. Prostap SR DCS is also indicated for endometrial preparation prior to intrauterine surgery; preoperative management of uterine fibroids to reduce their size and associated bleeding. **Dosage and Administration: Prostate Cancer:** Prostap SR DCS: 3.75mg administered every month as a single subcutaneous or intramuscular injection. Prostap 3 DCS: 11.25mg every 3 months as a single subcutaneous injection. Do not discontinue when remission or improvement occurs. Response to therapy should be monitored clinically. If response appears to be sub-optimal, it should be confirmed that serum testosterone is at castrate level. **Endometriosis:** Prostap SR DCS: 3.75mg administered as a single subcutaneous or intramuscular injection every month. Prostap 3 DCS: 11.25mg as a single intramuscular injection every 3 months. Treatment should be for a period of 6 months only and initiated during the first 5 days of the menstrual cycle. If appropriate, hormone replacement therapy (HRT - an oestrogen and progestogen) should be co-administered with Prostap DCS to reduce bone mineral density loss and vasomotor symptoms. **Endometrial Preparation Prior to Intrauterine Surgery:** Prostap SR DCS: 3.75mg as a single subcutaneous or intramuscular injection 5-6 weeks prior to surgery. Therapy should be initiated during days 3 to 5 of the menstrual cycle. **Preoperative Management of Uterine Fibroids:** Prostap SR DCS: 3.75mg as a single subcutaneous or intramuscular injection every month, usually for 3-4 months but for a maximum of six months. **Elderly:** as for adults. **Children** (under 18 years)**: Not Recommended** - safety and efficacy in children have not been established. For chronic administration, the injection site should be varied periodically. **Contraindications:** hypersensitivity to the active substance, any of the excipients or to synthetic GnRH or GnRH-derivatives. **Women:** lactation, pregnancy, undiagnosed abnormal vaginal bleeding. **Precautions and Warnings: General:** development or aggravation of diabetes may occur; therefore diabetic patients may require more frequent monitoring of blood glucose. Hepatic dysfunction and jaundice with elevated liver enzyme levels have been reported; therefore close observation should be made and appropriate measures taken if necessary. The ability to drive may be impaired due to visual disturbances and dizziness. **Men:** a transient rise in levels of testosterone may occur initially. This may be associated with tumour flare, sometimes manifesting as systemic or neurological symptoms. These symptoms usually subside on continuation of therapy. An anti-androgen may be administered to reduce the risk of flare (see SmPC, section 4.4). Patients at risk of ureteric obstruction or spinal cord compression should be closely supervised in the first few weeks of treatment. These patients should be considered for prophylactic treatment with anti-androgens. Should urological/neurological complications occur, these should be treated appropriately. **Women:** whilst ovulation is usually inhibited during therapy, contraception is not ensured. Patients should therefore use non-hormonal methods of contraception. During the early phase of therapy, sex steroids temporarily rise, possibly leading to an increase in symptoms, which dissipate with continued therapy. Menstruation should stop with effective doses of Prostap DCS; therefore the patient should notify her physician if regular menstruation persists. The induced hypo-oestrogenic state may result in a small loss in bone mineral density over the course of treatment, some of which may not be reversible. However, during one six-month treatment period, this bone loss should not be important. In patients with major risk factors for decreased bone mineral content, Prostap DCS may pose an additional risk. Before treating these patients for fibroids, their bone density should be measured, and where results are below the normal range, Prostap DCS therapy should not be started. In women receiving GnRH analogues for the treatment of endometriosis, the addition of HRT (an oestrogen and progestogen) has been shown to reduce bone mineral density loss and vasomotor symptoms. Prostap DCS may cause an increase in uterine cervical resistance. This may result in some difficulty in dilating the cervix for intrauterine surgical procedures. Diagnosis of fibroids must be confirmed prior to treatment, by laparoscopy, ultrasonography or other investigative technique. In women with submucous fibroids there have been reports of severe bleeding following administration of Prostap DCS, as a consequence of acute submucous fibroid degeneration. Patients should be warned of the possibility of abnormal bleeding or pain, in case earlier surgical intervention is required. **Side Effects: Refer to section 4.8 of the SmPC in relation to other side effects** - very rare cases of pituitary apoplexy have been reported following initial administration in patients with pituitary adenoma. **General:** adverse events which have been reported infrequently include peripheral oedema, pulmonary embolism, hypertension, palpitations, fatigue, muscle weakness, diarrhoea, nausea, vomiting, anorexia, fever/chills, headache (occasionally severe), hot flushes, arthralgia, myalgia, dizziness, insomnia, depression, paraesthesia, visual disturbances, weight changes, hepatic dysfunction, jaundice, and increases in liver function test values (usually transient). Reactions at the injection site have been reported rarely. Changes in blood lipids and alteration of glucose tolerance have been reported which may affect diabetic control. Thrombocytopenia and leucopenia have been reported rarely. Hypersensitivity reactions including rash, pruritus, urticaria, and rarely, wheezing or interstitial pneumonitis have also been reported. Bone mass reduction may occur. Anaphylactic reactions are rare. Spinal fractures, paralysis, hypotension and worsening of depression have been reported. **Men:** if tumour flare occurs, symptoms and signs due to disease may be exacerbated e.g. bone pain, urinary obstruction, weakness of the lower extremities and paraesthesia. These symptoms subside on continuation of therapy. Impotence and decreased libido will be expected with Prostap DCS therapy. Hot flushes and sometimes sweating are often associated with administration with Prostap DCS. Orchiatrophy and gynaecomastia have been reported occasionally. **Women:** side-effects reported are mainly those related to hypo-oestrogenism e.g. hot flushes, mood swings, including depression (occasionally severe) and vaginal dryness. Breast tenderness or a change in breast size, and hair loss, may occur occasionally. A small loss in bone density may also occur, some of which may not be reversible (see Precautions and Warnings). Vaginal haemorrhage may occur due to acute degeneration of submucous fibroids. **Legal Category:** POM. **Package Quantities:** Prostap SR DCS: one dual chamber pre-filled syringe containing 3.75mg leuprorelin acetate powder in the front chamber and 1ml of sterile solvent in the rear chamber. One 25 gauge needle, one syringe plunger and one injection site swab are included in a single injection pack. Prostap 3 DCS: one dual chamber pre-filled syringe containing 11.25mg leuprorelin acetate powder in the front chamber and 1ml of sterile solvent in the rear chamber. One 23 gauge needle, one syringe plunger and one injection site swab are included in a single injection pack. **Basic NHS Cost:** Prostap SR DCS £75.24; Prostap 3 DCS £225.72. **Marketing Authorisation Numbers:** Prostap SR DCS: 16189/0012; Prostap 3 DCS: 16189/0013. For full prescribing information and details of other side effects, see Summary of Product Characteristics. **Full prescribing information is available on request from:** Takeda UK Limited, Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Bucks, HP10 0HH, UK. Telephone: 01628 537900; Fax: 01628 526617. **Date of Prescribing Information:** September 2011. *Registered Trademark of Takeda. PS110937.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Takeda UK Ltd on 01628 537900.

References:
1. Prostap SR DCS. Summary of product characteristics.
2. Prostap 3 DCS. Summary of product characteristics.