Takeda

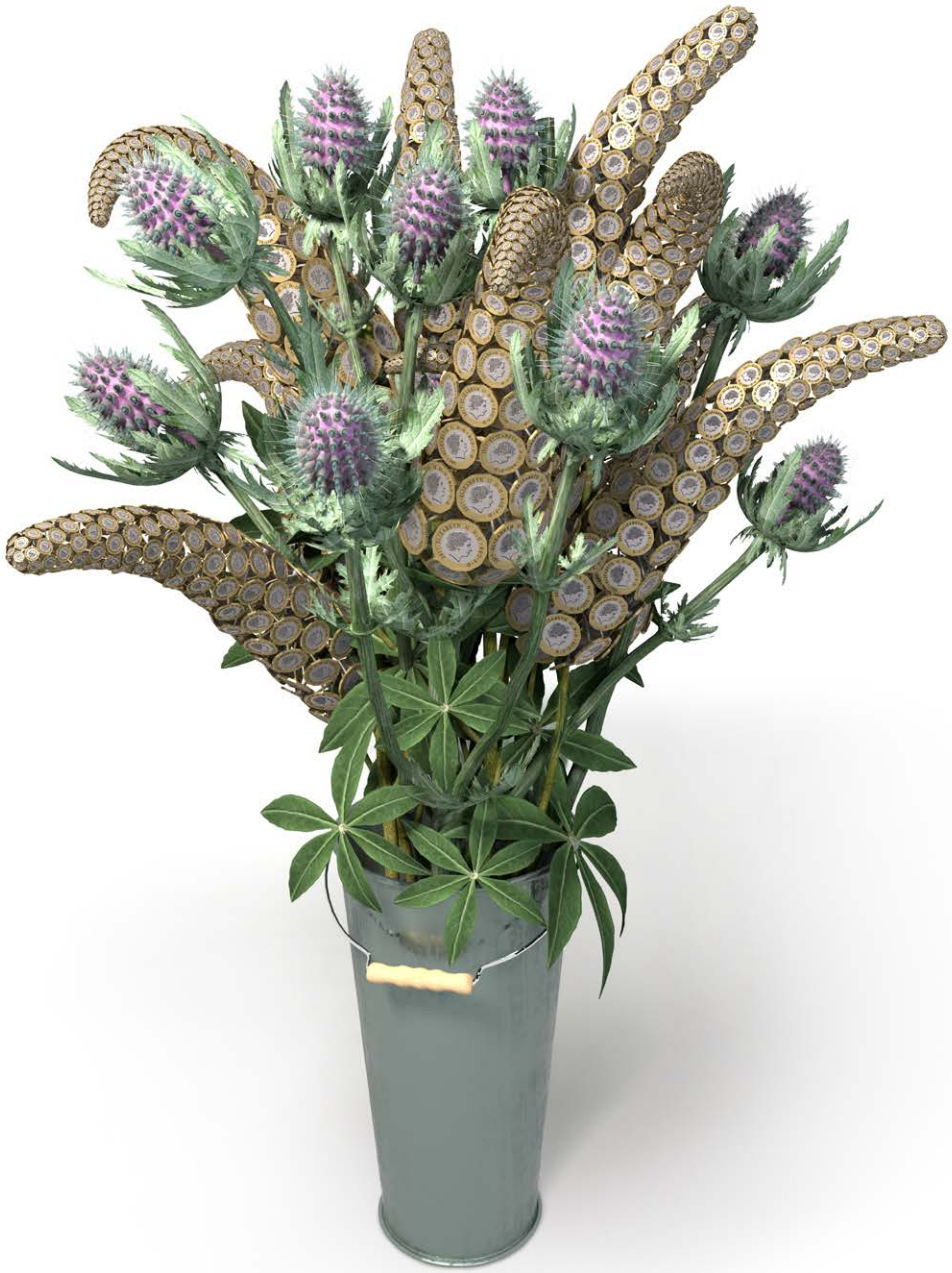
Prostap® DCS

leuprorelin acetate dual chamber syringe

Pro patient. Pro practice. Pro you

Pick Prostap DCS

for an exclusive discount for Somerset LMC



Prostap DCS prescribing information is available on the back cover.

Boost practice income by ordering Prostap DCS through CLARITYpharma

As the preferred partner of Takeda, CLARITYpharma is offering all practice members of the Somerset LMC a special member £30% discount for direct orders of Prostap DCS. This provides a profit of £69.74 per each 3-monthly injection.*

*Profit per each 3-monthly injection is based on a non-dispensing practice using a clawback rate of 5.93%.

30% discount off NHS list price

No sign-up fee

Register and order online, by phone, or email

Claim it through the normal FP34D process

For any queries on ordering Prostap DCS, please contact Claritypharma:

enquiries@clarity-pharma.com
www.clarity-pharma.com
0845 080 5190

For any enquires about how Prostap DCS can impact your practice income please contact Alveo Solutions:

info@alveosolutions.com
02381 850 089

Prostap® DCS

leuprorelin acetate dual chamber syringe

Pro patient. Pro practice. Pro you

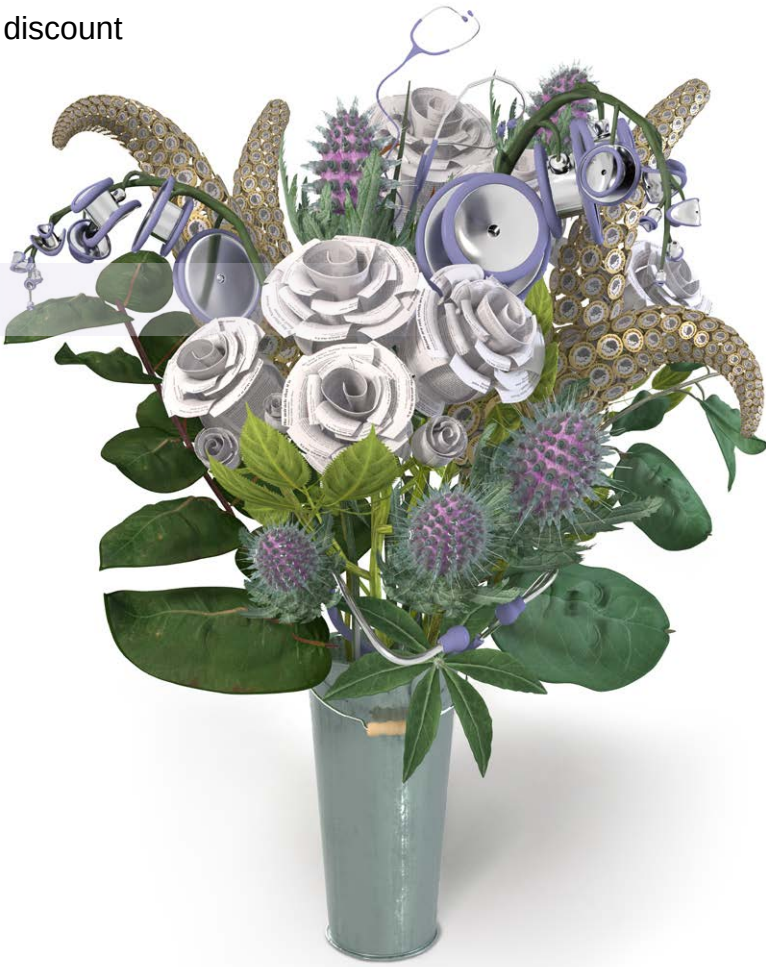
Let your practice benefit from all the **Pros of Prostap DCS**

Pro patient

- Smallest needle of all LHRH agonists[1-9]
- Support materials for you and your patients

Pro practice

- Prescribe and administer in one sitting[1,2]
- Personally administered (PA) item attracting 30% discount through CLARITYpharma



Pro you

- Complete parity of licensed indications in prostate cancer with Zoladex® (goserelin acetate) and Decapeptyl® (triptorelin acetate) makes switching to Prostap DCS easy.[1-7]
- The experience of leuprorelin[10]

Prescribing information

PROSTAP SR DCS/ PROSTAP 3 DCS leuprorelin acetate depot injection 3.75mg/11.25mg PRESCRIBING INFORMATION. Refer to Summaries of Product Characteristics (SmPC) before prescribing. Presentation: Prostap SR: leuprorelin acetate 3.75mg powder, equivalent to 3.57mg base, powder and solvent for prolonged-release suspension for injection in pre-filled syringe with safety device. **Prostap 3 DCS:** leuprorelin acetate 11.25mg equivalent to 10.72mg base, powder and solvent for prolonged-release suspension for injection in pre-filled syringe with safety device. **Indications: Prostap SR DCS/Prostap 3 DCS:** adjuvant to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression; adjuvant to or neo-adjuvant prior 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; treatment of central precocious puberty (girls under 9 years of age, boys under 10 years of age). **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 & 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 should be monitored clinically and if sub-optimal, check serum testosterone is at castrate level. In patients treated with GnRH analogues for prostate cancer, treatment is usually continued upon development of castrate-resistant prostate cancer. Reference should be made to relevant guidelines. **Central precocious puberty:** treatment of children with Prostap DCS should be under the overall supervision of the paediatric endocrinologist. **Prostap SR DCS:** *Children with a body weight ≥ 20 kg*: 3.75 mg administered once a month as a single subcutaneous injection. *Children with a body weight < 20 kg*: 1.88 mg administered once a month as a single subcutaneous injection. The administration interval should be 30 ± 2 days in order to prevent the recurrence of precocious puberty symptoms. **Prostap 3 DCS:** *Children with a body weight ≥ 20 kg*: 11.25 mg administered every 3 months as a single subcutaneous injection. *Children with a body weight < 20 kg*: 5.625 mg administered every 3 months as a single subcutaneous injection. The administration interval should be 90 ± 2 days in order to prevent the recurrence of precocious puberty symptoms. Injection site should be varied periodically. 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. Injection site should be varied periodically. **Contraindications:** hypersensitivity to the active substance, any of the excipients or to synthetic GnRH or GnRH-derivatives. Women and In girls with central precocious puberty: lactation; pregnancy; undiagnosed abnormal vaginal bleeding. **Warnings & Precautions:** aggravation of diabetes may occur; more frequent blood glucose monitoring recommended in diabetic patients. Hepatic dysfunction and jaundice with elevated liver enzyme levels reported; close observation recommended. Spinal fractures, paralysis, hypotension, worsening of depression have been reported. Patients at high risk for metabolic or cardiovascular diseases should be appropriately monitored. Postmarketing reports of seizures have been reported in both children and adults, and in those with or without a history of epilepsy, seizure disorders or risk disorders for seizures. Men: prophylactic antiandrogen use should be considered for patients at risk of ureteric obstruction or spinal cord compression. In the rare event of an abscess occurring at the injection site, testosterone level should be monitored as there may be inadequate absorption of leuprorelin from the depot formulation. May increase risk of bone loss, particular caution in patients with additional risk factors for osteoporosis. May prolong QT interval - particular caution in patients with a history of /or risk factors for QT prolongation or receiving concomitant medicinal products that might prolong the QT interval. Women: patients should ensure use of non-hormonal contraception in addition to being on treatment. Initial worsening of symptoms may occur due to initial increase in sex steroids, which dissipate with continued therapy. Patients should notify physician if regular menstruation persists; small loss in bone mineral density may occur. Do not use Prostap DCS in patients with bone density levels below the normal range (5th percentile by DEXA scan). Prostap DCS may cause an increase in uterine cervical resistance. 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. In girls with central precocious puberty: a precise diagnosis of idiopathic and/or neurogenic central precocious puberty is necessary. The occurrence of vaginal bleeding, spotting and discharge after the first injection may occur as a sign of hormone withdrawal in girls. Bone mineral density (BMD) may decrease during GnRH therapy for central precocious puberty. Slipped femoral epiphysis can be seen after withdrawal of GnRH treatment. **Interactions:** no studies performed. Carefully evaluate use with medicines that prolong QT interval or induce Torsade de pointes. **Fertility, Pregnancy & Lactation:** breastfeeding: should not be used. Patients should see their physician if they suspect a pregnancy. Discontinue treatment if patient becomes pregnant whilst on treatment. **Undesirable Effects:** Men: if tumour flare occurs, symptoms and signs due to disease may exacerbate e.g. bone pain and urinary obstruction, which should subside on continuation of therapy. Very Common (≥1/10): weight fluctuation, hot flush, hyperhydrosis, muscle weakness, bone pain, libido decreased, erectile dysfunction, testicular atrophy, fatigue, injection site reaction e.g. induration erythema, pain, abscesses, swelling, nodules, ulcers and necrosis. Common (≥1/100 to <1/10): decreased appetite, insomnia, depression, mood changes (long-term use), headache (occasionally severe), nausea, hepatic function abnormal, liver function test abnormal (usually transient), arthralgia, gynaecomastia and oedema peripheral. Frequency not known: lipids abnormal, glucose tolerance abnormal. Other serious undesirable effects (frequency not known): anaemia, thrombocytopenia, hypersensitivity reactions (including rash, pruritus, urticaria and rarely, wheezing or interstitial pneumonitis, anaphylactic reactions), paralysis, seizure, electrocardiogram QT prolonged, pulmonary embolism, jaundice, spinal fracture and interstitial lung disease. Refer to the SmPC for details on full side effect profile. Women: adverse events occurring most frequently with Prostap SR DCS and Prostap 3 DCS are associated with hypo-estrogenism. Most frequently reported are hot flushes, mood swings including depression (occasionally severe), and vaginal dryness. Oestrogen levels return to normal after treatment is discontinued. Vaginal haemorrhage may occur during therapy due to acute degeneration of submucous fibroids. Very Common (≥1/10): insomnia, headache (occasionally severe), hot flush. Common (≥1/100 to <1/10): weight fluctuation, mood altered depression, paresthesiae, dizziness, nausea, arthralgia, muscle weakness, breast tenderness, breast atrophy, vulvovaginal dryness, oedema peripheral, injection site reaction e.g. injection site induration, erythema, pain, abscesses, swelling, nodules, ulcers and necrosis. Frequency not known: glucose tolerance abnormal, which may affect diabetic control. Other serious undesirable effects: very rare (<1/10,000) pituitary haemorrhage following initial administration in patients with pituitary adenoma. Frequency not known: anaemia, thrombocytopenia, hypersensitivity reactions (including rash, pruritus, urticaria and rarely, wheezing or interstitial pneumonitis, anaphylactic reactions), paralysis, seizure, pulmonary embolism, jaundice, spinal fracture, interstitial lung disease and vaginal haemorrhage. Refer to the SmPC for details on full side effect profile. In children: In the initial phase of therapy, a short-term increase as flare-up of the sex hormone level occurs, followed by a decrease to values within the pre-pubertal range. Due to this pharmacological effect, adverse events may occur particularly at the beginning of treatment. Common (≥1/100 to <1/10): emotional liability, headache, abdominal pain/abdominal cramps, nausea/vomiting, acne, vaginal haemorrhage, spotting, vaginal discharge and injection site reactions. Other serious undesirable effects: very rare (<1,10,000) hypersensitivity (fever, rash, e.g. itching, anaphylactic reactions) and pituitary haemorrhage following initial administration in patients with pituitary adenoma. Frequency not known: seizure and interstitial lung disease. Refer to the SmPC for details on full side effect profile and interactions. **Basic NHS Price: Prostap SR DCS** £75.24; **Prostap 3 DCS** £225.72. **Legal Classification:** POM. **Marketing Authorisation Numbers: Prostap SR DCS:** 16189/0012; **Prostap 3 DCS:** 16189/0013. Further information is available from Takeda UK Ltd, Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Bucks, HP10 0DF. Tel 01628 537900. Fax 01628 526617. **PI Approval Code:** UK/PRS/1510/0055(2). **Date of Revision:** July 2018.

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

References

1. Prostap 3 DCS. Summary of Product Characteristics. Last accessed July 2020.
2. Prostap SR DCS. Summary of Product Characteristics. Last accessed July 2020.
3. Decapeptyl SR 3mg. Summary of Product Characteristics. Last accessed July 2020.
4. Decapeptyl SR 11.25mg. Summary of Product Characteristics. Last accessed July 2020.
5. Decapeptyl SR 22.5mg. Summary of Product Characteristics. Last accessed July 2020.
6. Zoladex 3.6mg. Summary of Product Characteristics. Last accessed July 2020.
7. Zoladex LA 10.8mg. Summary of Product Characteristics. Last accessed July 2020.
8. Lutrate 3.75mg. Summary of Product Characteristics. Available at medicines.org.uk. Last accessed July 2020.
9. Lutrate 22.5mg. Summary of Product Characteristics. Available at medicines.org.uk. Last accessed July 2020.
10. Takeda UK Ltd. Data on file. 120604(2).

Job code: UK/PRS/1902/0005a(1)
Date of preparation: July 2020