Prescribing Information
DECAPEPTYL® SR (triptorelin) 3mg, DECAPEPTYL® SR (triptorelin) 11.25mg and DECAPEPTYL® SR (triptorelin) 22.5mg

See full summary of product characteristics (SmPC) before prescribing. Available at www.medicines.org.uk.

Presentation: Powder and solvent for suspension for injection, sustained release formulation. Vials for all preparations contain an overage to ensure the licensed dose is administered. *Decapeptyl SR 3mg:* Triptorelin acetate 4.2mg. *Decapeptyl SR 11.25mg:* Triptorelin pamoate 15mg. *Decapeptyl SR 22.5mg:* Triptorelin pamoate 28mg.

Indications: Treatment of locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration. Treatment of metastatic prostate cancer. As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. As neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. As adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression.

Dosage and Administration: *Decapeptyl SR 3mg:* One intramuscular (IM) injection every four weeks (28 days). *Decapeptyl SR 11.25mg:* One IM injection every 3 months. *Decapeptyl SR 22.5mg:* One IM injection every 6 months (24 weeks). *Additional dosing information*: In patients treated with gonadotropin releasing hormone (GnRH) analogues for metastatic prostate cancer, treatment is usually continued upon development of castrate-resistant prostate cancer (see relevant guidelines). No dosage adjustment necessary in the elderly (Decapeptyl SR 3mg and 11.25mg) or for patients with renal or hepatic impairment (Decapeptyl SR 22.5mg). The injection site should be varied periodically. Inadvertent intravascular administration must be strictly avoided.

Contraindications: Hypersensitivity to GnRH, its analogues or any of the excipients.

Precautions and Warnings: The use of GnRH agonists may cause a reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with a GnRH agonist may reduce bone mineral loss. No specific data is available for patients with established osteoporosis or with risk factors for osteoporosis (e.g. chronic alcohol abuse, smokers, long-term therapy with drugs that reduce bone mineral density, e.g. anti-convulsants or corticosteroids, family history of osteoporosis, malnutrition, e.g. anorexia nervosa). Particular caution is therefore necessary since reduction in bone mineral density is likely to be more detrimental in these patients. Treatment with Decapeptyl SR should be considered on an individual basis and only be initiated if the benefits of treatment outweigh the risk following a very careful appraisal. Consideration should be given to additional measures in order to counteract loss of bone mineral density. Rarely, treatment with GnRH agonists may reveal the presence of a previously unknown gonadotroph cell pituitary adenoma. These patients may present with a pituitary apoplexy characterised by sudden headache, vomiting, visual impairment and ophthalmoplegia. There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as triptorelin. Patients should be informed accordingly and treated as appropriate if symptoms occur. Patients with known depression should be monitored closely during therapy. This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'. Caution is required with IM injection in patients treated with anticoagulants, due to the potential risk of haematomas at the site of injection. The efficacy and safety of Decapeptyl SR has been established via intramuscular route only. Initially, Decapeptyl SR, like other GnRH agonists, causes a transient increase in serum testosterone levels. As a consequence, isolated cases of transient worsening of signs and symptoms of prostate cancer (tumour flare) and cancer related (metastatic) pain may occasionally develop during the first weeks of treatment and should be managed symptomatically. During the initial phase of treatment, consideration should be given to the additional administration of a suitable anti-androgen to counteract the initial rise in serum testosterone levels and the worsening of clinical symptoms. As with other GnRH agonists, isolated cases of spinal cord compression or urethral obstruction have been observed. Careful monitoring is indicated during the first weeks of treatment, particularly in patients suffering from vertebral metastases, at risk of spinal cord compression, and in patients with urinary tract obstruction. After surgical castration, Decapeptyl SR does not induce any further decrease in serum testosterone levels. Long-term androgen is associated with increased risk of bone loss and may lead to osteoporosis and increased risk of bone fracture. Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT prolongation and in those receiving concomitant drugs that might prolong the QT interval, physicians should assess the benefit risk ratio including the potential for torsade de pointes prior to initiating treatment. From epidemiological data, it has been observed that patients may experience metabolic changes (e.g. glucose intolerance), or an increased risk of cardiovascular disease during androgen deprivation therapy (ADT). Patients at high risk for metabolic or cardiovascular diseases should be carefully assessed before commencing treatment and their glucose, cholesterol and blood pressure adequately monitored during ADT at appropriate intervals not exceeding 3 months. Administration of triptorelin in therapeutic doses results in suppression of the pituitary gonadal system. Normal function is usually restored after treatment is discontinued. Diagnostic tests of pituitary gonadal function conducted during and after discontinuation of therapy with GnRH agonists may therefore be misleading. **Interactions**: Drugs which raise prolactin levels should not be prescribed concomitantly as they reduce the level of GnRH receptors in the pituitary. When Decapeptyl SR is co-administered with drugs affecting pituitary secretion of gonadotropins, caution should be exercised and it is recommended that the patient's hormonal status be supervised. Since androgen deprivation therapy may prolong the QT interval, concomitant use of Decapeptyl SR with drugs known to prolong the QT interval or able to induce torsade de pointes, such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmics, methadone, moxifloxacin, antipsychotics etc. should be carefully evaluated.

Undesirable effects: *Very common (≥1/10):* Asthenia, hyperhidrosis, libido decreased, back pain, paraesthesia in lower limbs, erectile dysfunction, hot flush. *Common (≥1/100 to < 1/10):* Hypersensitivity, hypertension, dry mouth, nausea, injection site reaction (including erythema, inflammation, pain), oedema, musculoskeletal pain, pain in extremity, pelvic pain, dizziness, headache, depression, mood change, weight increased, loss of libido. *Uncommon (≥1/1000 to < 1/100):* includes diabetes mellitus, dyspnoea, urinary retention. *Rare (≥ 1/10000 to < 1/1000):* includes anaphylactic reaction. *Post-marketing (frequency not known):* Anaphylactic shock, pituitary apoplexy, anxiety, QT prolongation, angioneurotic oedema, urinary incontinence, malaise.
Prescribers should consult the Summary of Product Characteristics in relation to other side effects.

Overdosage: If overdose occurs, symptomatic management is indicated. **Pharmaceutical Precautions:** Do not store above 25ºC. Reconstitute only with the suspension vehicle provided. Decapeptyl SR is a suspension, therefore once reconstituted, it should be used immediately to prevent precipitation.

Legal Category: POM.

Basic NHS cost: *Decapeptyl SR 3mg* £69.00 per vial. *Decapeptyl SR 11.25mg* £207.00 per vial. *Decapeptyl SR 22.5mg* £414.00 per vial.

Marketing Authorisation *Numbers*: *Decapeptyl SR 3mg*: PL 34926/0002. *Decapeptyl SR 11.25mg*: PL 34926/0003. *Decapeptyl SR 22.5mg* PL 34926/0013.

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Ipsen via email at pharmacovigilance.uk-ie@ipsen.com or phone on 01753 627777