Eligard (leuprorelin acetate)

Prescribing Information. The summary of medicinal product characteristics (SmPC) should be consulted for full details. **Name of the medicinal product** Eligard 22.5 mg powder and solvent for solution for injection. Eligard 45 mg powder and solvent for solution for injection. **Pharmaceutical form** Powder and solvent for solution for injection. Powder (Syringe B): Pre-filled syringe with a white to off-white powder. Solvent (Syringe A): Prefilled syringe with a clear, colourless to pale yellow solution. **Therapeutic indications** Eligard is indicated for the treatment of hormone-dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy. **Posology** Eligard should be administered under the direction of a healthcare professional having available the appropriate expertise for monitoring the response to treatment. Eligard 22.5 mg is administered as a single subcutaneous injection every 3 months. Eligard 45 mg is administered as a single subcutaneous injection every 6 months. As a rule, therapy of advanced prostate cancer with Eligard entails long-term treatment and therapy should not be discontinued when remission or improvement occurs. Response to Eligard should be monitored by clinical parameters and by measuring prostate specific antigen (PSA) serum levels. Clinical studies have shown that testosterone levels increase during the first 3 days of treatment in the majority of non-orchiectomised patients and then decreased to below medical castration levels within 3 - 4 weeks. In case the patient's response appears to be sub-optimal, it should be confirmed that serum testosterone levels have reached or are remaining at castrate levels. As lack of efficacy may result from incorrect preparation, reconstitution, or administration, testosterone levels should be evaluated in cases of suspected or known handling errors. In patients with metastatic castration-resistant prostate cancer not surgically castrated receiving a GnRH agonist, such as leuprorelin, and eligible for treatment with androgen biosynthesis inhibitors or androgen receptor inhibitors, treatment with a GnRH agonist may be continued. **Paediatric population** The safety and efficacy of Eligard in children aged 0 to 18 years have not been established. **Specific Patient Populations** No clinical studies were performed in patients with either liver or kidney impairment. **Method of administration** Instructions for reconstitution and administration must be strictly followed (see SmPC). If the product is not prepared appropriately, it should not be administered. The contents of the pre-filled sterile syringes must be mixed immediately prior to administration of Eligard by subcutaneous injection. Based on data from animal experience, intra-arterial or intravenous injection, respectively, has to be strictly avoided. As with other medicinal products administered by subcutaneous injection, the injection site should be varied periodically. **Contraindications** Women and paediatric patients. Hypersensitivity to leuprorelin acetate, to other GnRH agonists, or to any of the excipients. Patients who previously underwent orchiectomy. As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases. **Special warnings and precautions for use** Correct reconstitution: Cases of handling errors which can occur during any step of the preparation process, and which could potentially result in lack of efficacy have been reported. Instructions for reconstitution and administration must be strictly followed. In cases of suspected or known handling error, patients should be monitored appropriately. Androgen deprivation therapy may prolong the QT interval: In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating Eligard. Cardiovascular diseases: Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. The risk appears low based on the reported odds ratios and should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Transient testosterone flare: Leuprorelin acetate, like other GnRH agonists, causes a transient increase in serum concentrations of testosterone, dihydrotestosterone, and acid phosphatase during the first week of treatment, which usually subsides on continuation of therapy. Additional administration of an appropriate antiandrogen should be considered beginning 3 days prior to leuprorelin therapy and continuing for the first two to three weeks of treatment. Following surgical castration, Eligard does not lead to a further decrease in serum

testosterone levels in male patients. Bone density: Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with GnRH agonists. The risk for fractures owing to osteoporosis is generally higher than the risk for pathological fractures. Apart from long-lasting testosterone deficiency, increased age, smoking and consumption of alcoholic beverages, obesity, and insufficient exercise may have an influence on the development of osteoporosis. Pituitary apoplexy: During post-marketing surveillance, rare cases of pituitary apoplexy have been reported after the administration of GnRH-agonists, with a majority occurring within 2 weeks of the first dose, and some within the first hour. Immediate medical attention is required. Hyperglycemia and diabetes: Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Metabolic changes associated with GnRH agonists may also include fatty liver disease. Convulsions: Postmarketing reports of convulsions have been observed in patients on leuprorelin acetate therapy with or without a history of predisposing factors. Convulsions are to be managed according to the current clinical practice. Idiopathic intracranial hypertension: Idiopathic intracranial hypertension (pseudotumor cerebri) has been reported in patients receiving leuprorelin. Patients should be warned for signs and symptoms of idiopathic intracranial hypertension, including severe or recurrent headache, vision disturbances, and tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of leuprorelin should be considered. Severe cutaneous adverse reactions: Severe cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported with leuprorelin. Patients should be advised of signs and symptoms at prescription and monitored closely. If suggestive signs appear, withdraw leuprorelin immediately and consider alternative treatment. Other events: Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. If spinal cord compression or renal impairment develops, standard treatment of these complications should be instituted. Patients with vertebral and/or brain metastases as well as patients with urinary tract obstruction should be closely monitored during the first few weeks of therapy. **Interaction with other medicinal products and other forms of interaction** No pharmacokinetic drug-drug interaction studies have been performed with Eligard. There have been no reports of any interactions of leuprorelin acetate with other medicinal products. Since androgen deprivation treatment may prolong the QT interval, the concomitant use of Eligard with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated. **Fertility, pregnancy, and lactation** Not applicable as Eligard is contraindicated in women. **Effects on ability to drive and use machines** No studies on the effects of Eligard on the ability to drive and use machines have been performed. **Undesirable effects** Adverse reactions seen with Eligard are mainly subject to the specific pharmacological action of leuprorelin acetate, namely increases and decreases in certain hormone levels. **Very Common**: Hot flashes, Ecchymoses, Erythema, Fatigue, Injection site burning, Injection site paraesthesia. **Common**: Nasopharyngitis, Nausea, Diarrhoea, Gastroenteritis/colitis/dyspepsia, Pruritus, Night sweats, Arthralgia, Pain in extremity, Myalgia, Chills, Asthenia, Urinary frequency, Difficulty in micturation, Dysuria, Nocturia, Oliguria, Breast tenderness, Testicular atrophy, Testicular pain, Infertility, Breast enlargement, Erectile dysfunction, Reduced penis size, Malaise, Injection site pain, Injection site bruising, Haematology changes, Anaemia, Increased blood creatinine phosphokinase, Prolonged coagulation time. *In addition, adverse events which could be considered serious include* **Uncommon**: Urinary tract infection, Diabetes mellitus, Depression, Hypertension, Hypotension, Dyspnoea, Haematuria, Urinary retention, Prolonged prothrombin time; **Rare**: Syncope, Collapse; **Very rare**: Injection site necrosis; **Frequency not known:** QT prolongation, interstitial lung disease, idiopathic intracranial hypertension, Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), toxic skin eruption, erythema multiforme. Please consult the summary of product characteristics in relation to other adverse reactions. **Legal classification**: Product subject to medical prescription which may not be renewed (A) **Cost:** Eligard 22.5mg = £225; Eligard 45 mg = £450

Marketing authorisation holder: Recordati Industria Chimica e Farmaceutica S.p.A.Via Matteo Civitali, 11-20148 Milan Italy **Local Office in United Kingdom**: Recordati Pharmaceuticals Ltd, Breakspear Park, Hemel Hempstead, HP2 4TZ, United Kingdom **Marketing authorisation number(s)**: PL 04595/0030; PL 04595/0031. **Date of last revision**: January 2026 **Veeva reference**: UK-ELIGA-0008

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 Recordati Pharmaceuticals Ltd on Local-Safety@recordati.com

References:

1. Eligard® 22.5 mg. Summary of Product Characteristics

2. Eligard® 45 mg. Summary of Product Characteristics