

# A new level of control

# eligard<sup>®</sup>

leuporelin acetate



#### Abbreviated Product Information

Eligard<sup>®</sup> 7.5 mg, 22.5 mg and 45 mg, powder and solvent for solution for injection. **Composition** After reconstitution of the powder with the solvent the deliverable amount is 7.5 mg, 22.5 mg and 45 mg of leuporelin acetate.

**Indication** Treatment of hormone dependent advanced prostate cancer. **Posology** Eligard<sup>®</sup> 7.5 mg, administered every month subcutaneously. Eligard<sup>®</sup> 22.5 mg, administered every three months subcutaneously. Eligard<sup>®</sup> 45 mg, administered every six months subcutaneously. **Contraindications** Hypersensitivity to leuporelin acetate, other GnRH agonists or to any of the excipients. Patients who previously underwent orchiectomy (Eligard<sup>®</sup> does not result in further decrease of serum testosterone in case of surgical castration). As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases. Women and pediatric patients.

**Special warnings and special precautions for use** Leuporelin acetate causes a transient increase in serum concentrations of testosterone, dihydrotestosterone and acid phosphatase during the first week of treatment. This can lead to a transient worsening of symptoms (additional administration of an antiandrogen beginning 3 days prior to Eligard therapy and continuing for the first 2 to 3 weeks of treatment should be considered). Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. 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 treatment. If spinal cord compression or renal

impairment develops, standard treatment of these conditions should be instituted. Patients with hormone insensitive tumors will not benefit from further therapy with Eligard<sup>®</sup>. Decreased bone density has been reported in men who have had orchiectomy or who have been treated with a GnRH agonist. Antiandrogen therapy significantly increases the risk for fractures due to osteoporosis. As in some patients changes in glucose tolerance have been reported, diabetic patients should be monitored more frequently. **Undesirable effects** Adverse reactions seen with Eligard<sup>®</sup> are mainly subject to the specific pharmacological actions of leuporelin acetate, namely increase and decrease in certain hormone levels. The most commonly reported undesirable effects are hot flushes, malaise and fatigue, and transient local irritation. For more information, see registered SPC. Astellas Europe BV, PO Box 108, 2350 AC Leiderdorp, The Netherlands

#### Reference:

1. Crawford ED et al. *J Urol* 2006; 175: 533-536

\*Testosterone suppression of  $\leq 20$  ng/dL, achieved in up to 98% of patients throughout the whole treatment period, with minimal breakthroughs and no incremental side effects

