Eligard®
(leuprolide acetate) for injectable suspension

Clinical Summary

Class

ELIGARD® (leuprolide acetate) for injectable suspension, **is the only subcutaneously delivered injection** of gonadotropin releasing hormone **(GnRH) agonist with an extended-release technology**[1]

Indication

ELIGARD is indicated for the palliative treatment of advanced prostate cancer.

Dose Forms

ELIGARD provides flexible dosing options with technology that enables small injection volumes.[1]

Dosage	Injection Volume	Mean serum testosterone level*	Mean PSA reduction*
7.5 mg (every month)	0.25 mL	6.1 ng/dL	94%
22.5 mg (every 3-months)	0.375 mL	10.1 ng/dL	98%
30 mg (every 4-months)	0.50 mL	12.4 ng/dL	86%
45 mg (every 6-months)	0.375 mL	12.6 ng/dL	97%

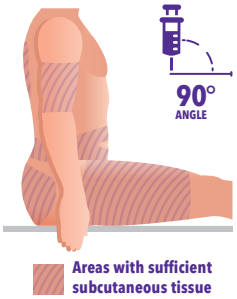
*At study conclusion

Storage

Store at 2 – 8 °C (35.6 – 46.4 °F). Once outside the refrigerator this **product may be stored in its original packaging at room temperature 15 – 30 °C (59 – 86 °F) for up to eight weeks** prior to mixing and administration.

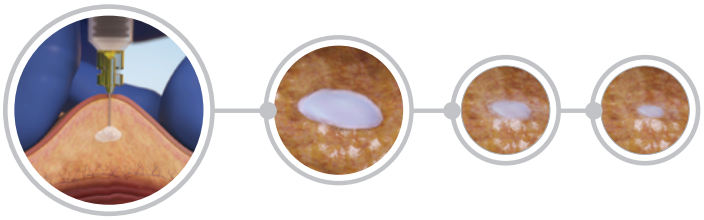
Administration

Any subcutaneous region with adequate amounts of subcutaneous tissue. Avoid areas with brawny or fibrous subcutaneous tissue or locations that could be rubbed or compressed.



Drug Delivery

ELIGARD delivers leuprolide acetate through a unique, in-situ polymeric gel extended-release technology[2]



Package Dimensions

3″ (w) x 5 ½″ (h) x 2 ¼″ (d)

USP General Chapter <800> Considerations

USP General Chapter <800> is only applicable in the context of compounding. ELIGARD is a conventionally manufactured product, and preparation in accordance with the approved labeling for administration to an individual patient is not considered compounding. **Therefore, USP General Chapter <800> does not apply to the mixing and administration of ELIGARD.**

Relevant Codes

ELIGARD 7.5 mg	ELIGARD 22.5 mg	ELIGARD 30 mg	ELIGARD 45 mg
NDC: 62935-753-75	**NDC:** 62935-223-05	**NDC:** 62935-303-30	**NDC:** 62935-453-45
J-Code: J9217	**CPT:** 96402	**Outpatient CPT:** Q0083 OPPS†	**ICD-10:** C61

†OPPS: Outpatient Perspective Payment System

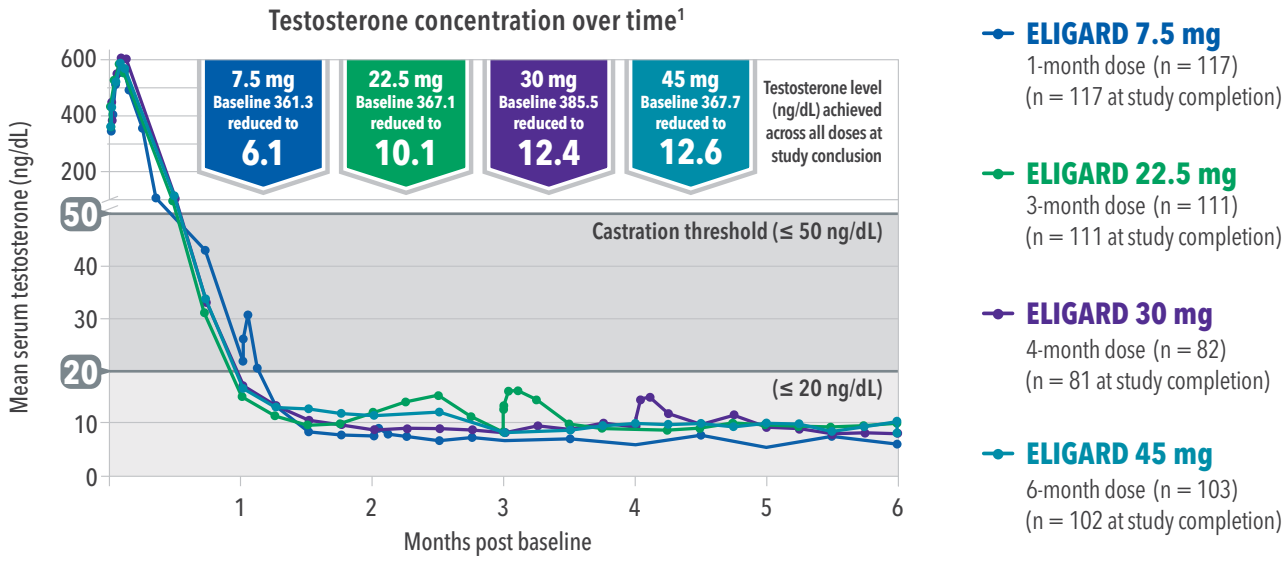
IMPORTANT SAFETY INFORMATION

ELIGARD is indicated for the palliative treatment of advanced prostate cancer.

ELIGARD is contraindicated in patients with hypersensitivity to GnRH, GnRH agonist analogs, or any of the components of ELIGARD. Anaphylactic reactions to synthetic GnRH or GnRH agonist analogs have been reported in the literature. Transient increase in serum levels of testosterone during treatment may result in worsening of symptoms or onset of new signs and symptoms during the first few weeks of treatment, including bone pain, neuropathy, hematuria, bladder outlet obstruction, ureteral obstruction, or spinal cord compression.

See additional Important Safety Information on back and enclosed package insert for full Prescribing and Safety Information.

ELIGARD® delivers **powerful and sustained testosterone suppression** that reflects **current science.**



ELIGARD 7.5 mg
1-month dose (n = 117)
(n = 117 at study completion)

ELIGARD 22.5 mg
3-month dose (n = 111)
(n = 111 at study completion)

ELIGARD 30 mg
4-month dose (n = 82)
(n = 81 at study completion)

ELIGARD 45 mg
6-month dose (n = 103)
(n = 102 at study completion)

ELIGARD® (leuprolide acetate) for injectable suspension, achieves and maintains low castrate testosterone levels across all four doses, including the longest duration available (6-month dose).[1]

ELIGARD has a **well-tolerated safety profile.**[1]

Adverse events	**1-month** (7.5 mg)	**3-month** (22.5 mg)	**4-month** (30 mg)	**6-month** (45 mg)
Most common injection site reactions reported in ≥ 5% of injections				
Transient burning/stinging	34.6%	21.7%	20%	16%
Most common possibly or probably treatment-related systemic reactions reported in >2% of patients				
Hot flashes/sweats	56.7%	56.4%	73.3%	57.7%
Malaise and fatigue	17.5%	6.0%	13.3%	11.7%
Testicular atrophy	5.0%	≤2%	4.4%	7.2%

IMPORTANT SAFETY INFORMATION (continued)

Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH analogs. Monitor blood glucose level and manage according to current clinical practice. Increased risk of myocardial infarction, sudden cardiac death and stroke has also been reported with use of GnRH analogs in men. Monitor for cardiovascular disease and manage according to current clinical practice. Androgen deprivation therapy may prolong the QT/QTc interval. Consider risks and benefits. May cause fetal harm. Convulsions have been observed in patients taking leuprolide acetate with or without a history of predisposing factors. Manage convulsions according to current clinical practice.

ELIGARD may impair fertility in males of reproductive potential.

The most common injection site adverse events are transient burning and stinging, pain, bruising, and erythema. The most common systemic adverse events include mild to severe hot flashes/sweats, malaise and fatigue, weakness, myalgia, dizziness, clamminess, testicular atrophy, and gynecomastia. As with other GnRH agonists, other adverse reactions, including decreased bone density and rare cases of pituitary apoplexy have been reported.

See enclosed package insert for full Prescribing and Safety Information.

References:

1. ELIGARD® (leuprolide acetate) for injectable suspension, 7.5 mg, 22.5 mg, 30 mg, 45 mg prescribing information. Fort Collins, CO: Tolmar Therapeutics, Inc.; 2019

2. Sartor O. *Eur Urol* 2006

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tolmar