Cipla

Leuprolide Acetate Injection Depot

(Leuprolide Acetate for Depot Suspension)

22.5 mg*

*Each syringe contains 22.5 mg (provided as Leuprolide acetate)

To place your order, please contact your wholesaler:

WHOLESALER/DISTRIBUTOR ORDER ENTRY NUMBER			
AMERISOURCEBERGEN	CARDINAL	MCKESSON	MORRIS & DICKSON
10274981	5815139	2655967	190595

INDICATIONS AND USAGE[1]

LEUPROLIDE ACETATE INJECTION DEPOT (leuprolide acetate for depot suspension) 22.5 mg for 3-month administration (leuprolide acetate) is indicated for palliative treatment of advanced prostate cancer.

IMPORTANT SAFETY INFORMATION[1]

Contraindications: Hypersensitivity: LEUPROLIDE ACETATE INJECTION DEPOT is contraindicated in individuals with known hypersensitivity to GnRH agonists or any of the excipients in LEUPROLIDE ACETATE INJECTION DEPOT. Anaphylactic reactions to GnRH agonists have been reported.

Warnings And Precautions:

- **Tumor Flare:** LEUPROLIDE ACETATE INJECTION DEPOT causes increases in serum levels of testosterone during the first weeks of treatment. Isolated cases of ureteral obstruction and spinal cord compression have been observed, which may contribute to paralysis with or without fatal complications. Transient worsening of symptoms may develop. Patients may experience a temporary increase in bone pain. Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed.
- **Hyperglycemia and Diabetes:** Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH.
- **Cardiovascular Diseases:** Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported, and should be evaluated carefully along with cardiovascular risk factors. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed accordingly.
- **Effect on QT/QTc Interval:** Androgen deprivation therapy may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.
- **Convulsions:** Convulsions have been observed and should be managed accordingly.
- **Laboratory Tests:** Monitor serum levels of testosterone following injection of LEUPROLIDE ACETATE INJECTION DEPOT 22.5 mg for 3-month administration.
- **Embryo-Fetal Toxicity:** LEUPROLIDE ACETATE INJECTION DEPOT may cause fetal harm when administered to a pregnant woman. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.

Most common adverse events (incidences >10%) are hot flushes, upper respiratory infection, fatigue, diarrhea, pollakiuria, arthralgia, and injection site pain.

Use in specific populations:

Lactation: A decision should be made to discontinue breastfeeding or discontinue the LEUPROLIDE ACETATE INJECTION DEPOT.

Females and Males of Reproductive Potential: LEUPROLIDE ACETATE INJECTION DEPOT may impair fertility in males of reproductive potential.

Pediatric Use: The safety and effectiveness of LEUPROLIDE ACETATE INJECTION DEPOT in pediatric patients have not been established.

Geriatric Use: Hot flushes occurred with equal frequency in those ≤ 65 years of age.

To report suspected adverse reactions, contact Cipla at 1-866-604-3268 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the accompanying full Prescribing Information for Important Safety Information.

Medical Information:

Report Adverse Events/Side Effects | Report Product Complaints | Submit Medical Inquiries:

Contact Us: **1-866-604-3268** **DrugSafety@cipla.com**

www.ciplausa.com

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DETAILS	
NDC[1]	69097-909-50
STRENGTH[1]	22.5 mg
ROUTE OF ADMINISTRATION[1]	Intramuscular injection
SELLING UNIT	1 kit consisting of a LEUPROLIDE ACETATE INJECTION MIXJECT single-dose delivery system
SELLING UNITS PER SHIPPER CASE	80
STORAGE[1]	Store at controlled room temperature at 20°-25°C (68°-77°F); excursions permitted between 15°C and 30°C (59°C and 86°F) [see USP Controlled Room Temperature]
STORAGE AFTER RECONSTITUTION[1]	The suspension should be administered immediately after reconstitution
SHELF LIFE[2]	36 months from date of manufacture

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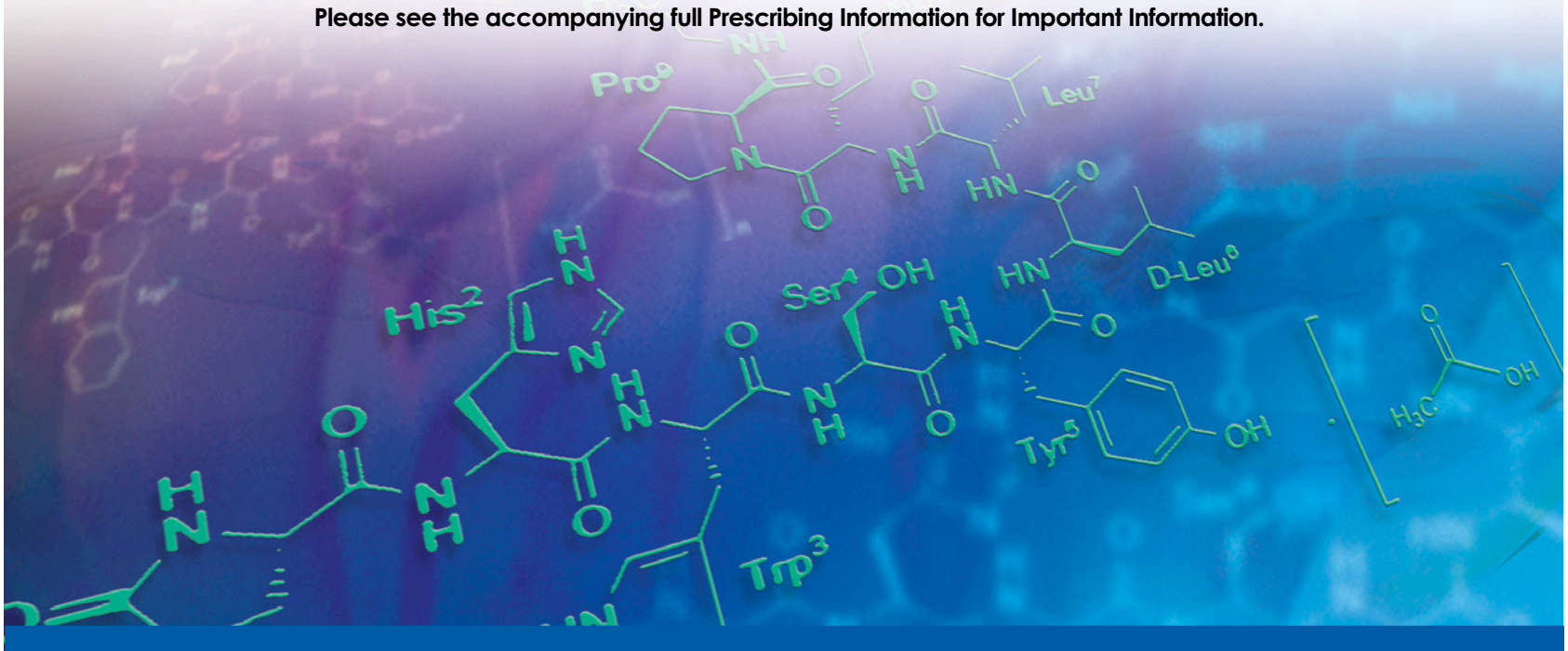
Please see the accompanying full Prescribing Information for Important Information.



REFERENCES:

1. LEUPROLIDE PRESCRIBING INFORMATION, CIPLA, 2018.
2. Data on file. CIP-REF-LEU-001. Warren, NJ: Cipla USA; 2022

Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059

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