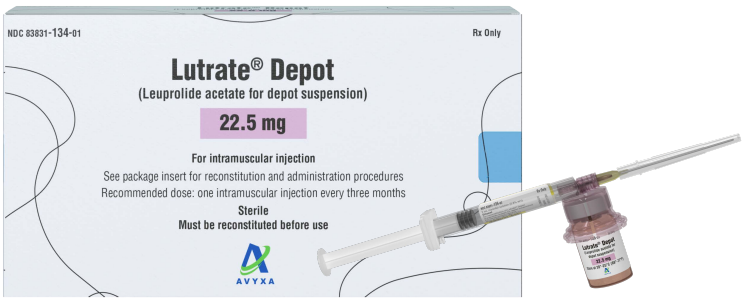
LUTRATE® DEPOT

(leuprolide acetate for depot suspension)

Ordering Information

To order LUTRATE® DEPOT (leuprolide acetate for depot suspension), please contact one of these authorized specialty distributors and use the appropriate order number:



22.5 mg
NDC: 83831-0134-01

Institutions/Hospitals	22.5 mg
Cardinal Health Specialty	5976659
CENCORA - ASD Healthcare	10302021
McKesson Plasma & Biologics	3033396
Physician Offices	**22.5 mg**
Cardinal Health Specialty	5976659
Oncology Supply	10301925
McKesson Specialty Health	5020163
Besse Medical	10302010

Highlights

UNIQUE J-CODE[4]
J1954

- LUTRATE® DEPOT is supplied as 22.5 mg of leuprolide acetate
- Intramuscular injection
- For 3-month administration
- No refrigeration required
- Supplied as a commercial kit. Each kit contains:
  - One vial containing 22.5 mg of leuprolide acetate as lyophilized microspheres
  - One prefilled syringe containing 2 mL of mannitol for injection
  - One MIXJECT transfer device including one 20-gauge needle

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information for LUTRATE® DEPOT.

AVYXASSIST™

Simplifying Patient Access, Providing Comprehensive Support.

AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services*

- Benefit verification
- Prior authorization requirements
- Appeals process information
- Referrals to 501(c)(3) foundations when applicable
- Free product assistance (uninsured or underinsured), bridge supply (coverage delays)
- Product replacement
- Copay assistance

COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as **$0** per dose*

TO ENROLL, PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS

Phone

866-939-8927
Monday through Friday
8 AM to 8 PM ET

CALL NOW

OR

Online

Click on the link below to begin your online enrollment

ENROLL NOW

OR

Fax

Download, print and fax the completed enrollment form to 833-852-3420

DOWNLOAD NOW

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information for LUTRATE® DEPOT.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

LUTRATE® DEPOT (leuprolide acetate), for depot suspension is a gonadotropin-releasing hormone (GnRH) agonist indicated for treatment of advanced prostate cancer.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Hypersensitivity: LUTRATE DEPOT is contraindicated in patients with known hypersensitivity to GnRH agonists or any of the excipients in LUTRATE DEPOT.

WARNINGS AND PRECAUTIONS

Tumor Flare: LUTRATE DEPOT, like other GnRH agonists, causes increases in serum levels of testosterone to approximately 50% above baseline during the first weeks of treatment. 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, which can be managed symptomatically.

Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed during the first few weeks of therapy.

Metabolic Syndrome: The use of GnRH agonists may lead to metabolic changes such as hyperglycemia, diabetes mellitus, and hyperlipidemia. Non-alcoholic fatty liver disease, including cirrhosis, occurred in the post-marketing setting. Hyperglycemia may represent new-onset diabetes mellitus or worsening of glycemic control in patients with pre-existing diabetes. Monitor for changes in serum lipids, blood glucose and/or glycosylated hemoglobin (HbA1c) in patients receiving a GnRH agonist and manage according to current treatment guidelines.

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 should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.

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 in patients on leuprolide acetate therapy. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above. Patients receiving a GnRH agonist who experience convulsion should be managed according to current clinical practice.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information for LUTRATE® DEPOT.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), may occur in patients receiving LUTRATE DEPOT; including cases with visceral involvement and/or requiring skin grafts.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (e.g., a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy).

If a SCAR is suspected, interrupt LUTRATE DEPOT until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other grade 4 skin reactions, permanently discontinue LUTRATE DEPOT.

Laboratory Tests: Monitor serum levels of testosterone following injection of LUTRATE DEPOT 22.5 mg for 3-month administration. In the majority of patients, testosterone levels increased above baseline during the first week, and then declined thereafter to castrate levels (< 50 ng/dL) within four weeks.

Embryo-Fetal Toxicity: LUTRATE 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.

ADVERSE REACTIONS

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

As with other GnRH agonist, other adverse reactions, including decreased bone density and rare cases of pituitary apoplexy may occur.

USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential: LUTRATE DEPOT may impair fertility. Counsel patients on pregnancy planning and prevention.

Pediatric: The safety and effectiveness of LUTRATE DEPOT in pediatric patients have not been established.

Please see full Prescribing Information of LUTRATE DEPOT.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

AVYXA