Leuprolide Acetate for Injection 3.75mg (Depot)

For Intramuscular / Subcutaneous use
Not for Intravenous Administration

**Dosage and Administration**

**LUPRODEX 3.75 mg (DEPOT)** is a sterile, lyophilized powder containing Leuprolide Acetate formulated as Microspheres. Each ml contains:

- Poly (D,L-lactide-co-glycolide) Biodegradable Polymer (TM) ............................... 100 mg
- Leuprorelin B.P. (As acetate) ............................... 3.75 mg

1. Leuprolide Acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**Contraindications**

**LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are pregnant while receiving the drug. **LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are nursing while receiving the drug.

**Hypersensitivity to GnRH, GnRH agonist analogs or its diluent.**

**Central Precocious Puberty (CPP):**

- **Clinical diagnosis should be confirmed prior to initiation of therapy with LUPRODEX 3.75 mg (DEPOT).**
- **UNLEED Prematuration** should be selected using the following criteria:
  - 3.75 mg (DEPOT) plus norethindrone acetate.
  - Tanner staging to confirm down regulation. Measurements of bone age and pubertal status should be used with caution in women with risk factors, including lipid abnormalities.

**Pediatric Use:** Experience with LUPRODEX 3.75 mg (DEPOT) for treatment of endometriosis has been limited to women 18-50 years of age. Experience with Leuprolide Acetate for Injection 3.75mg (Depot) for treatment of prostate cancer has been limited to men 45 years of age and older.

**Pharmacology:**

**Mechanism of Action:**

- **LUPRODEX 3.75 mg (DEPOT)** is a sterile, lyophilized powder containing Leuprolide Acetate formulated as Microspheres. **LUPRODEX 3.75 mg (DEPOT)** is to be reconstituted with accompanying diluent which forms a uniform suspension intended for intramuscular or subcutaneous injection to be administered once every month.

**Active ingredient:**

Leuprolide Acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**Indications:**

- **LUPRODEX 3.75 mg (DEPOT)** is indicated for the preoperative hematologic improvement of women with endometriosis, including pain relief and reduction of pelvic pain prior to surgical intervention. A course of treatment should be limited to 6 months.

**Leuprolide Acetate** is a synthetic analog of gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**Efficacy:**

- **LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are pregnant while receiving the drug. **LUPRODEX 3.75 mg (DEPOT)** may cause fetal harm when administered to a pregnant woman.

- **Unlabeled uses of intranasal administration:**
  - 3.75 mg (DEPOT) is used in combination with progestin to induce premature closure of the ductus arteriosus in newborns of Apparently Normal Gestational Age (PNA) weighing less than 1500 grams.

**Side Effects & Adverse Reactions:**

**3.75 mg (DEPOT) and norethindrone acetate.**

**Monitoring in Advanced Prostatic Cancer Patients:**

- **Color Cardiac System / Hypertension, Pulmonary embolism**
- **Blood & Lymphatic System / Decreased Hb/CRC**
- **Nervous System / Personality change, Sleep disorder, Gastrointestinal distress, and Headaches**
- **Musculoskeletal System / Tenosynovitis like symptoms; Urogenital System - Prostate pain,**

**Drug / Laboratory Test Interactions:**

- Leuprolide acetate for injection 3.75mg (Depot) is contraindicated in women who are nursing while receiving the drug.
- **LUPRODEX 3.75 mg (DEPOT)** plus norethindrone acetate.
- **LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are pregnant while receiving the drug. **LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are nursing while receiving the drug.

**Precautions & Warnings:**

- **Leuprolide Acetate** is a synthetic analog of GnRH. **LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are pregnant while receiving the drug. **LUPRODEX 3.75 mg (DEPOT)** may cause fetal harm when administered to a pregnant woman.

- **Unlabeled uses of intranasal administration:**
  - 3.75 mg (DEPOT) is used in combination with progestin to induce premature closure of the ductus arteriosus in newborns of Apparently Normal Gestational Age (PNA) weighing less than 1500 grams.

**DOSAGE AND ADMINISTRATION:**

**For the use only of Physician, Gynaecologist, Oncologist, and Urologist.**

**Leuprolide Acetate for Injection 3.75mg (Depot) 3.75 mg (DEPOT)**

**Dosage and Administration:**

1. Hypersensitivity to GnRH, GnRH agonist analog or its diluent.

**Leuprolide Acetate** is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**Adrenal Cortex:**

- **Adrenal cortex to level to exclude congenital adrenal hyperplasia.**

- **Beta HCG level to rule out a chronic gonadotropin secreting tumor.**

- **Pelvic / adrenal / testicular ultrasound to rule out a steroid producing tumor.**

- **Compartimental topography of the head to rule out intracranial tumor.**

**Hypersensitivity to GnRH, GnRH agonist analog or its diluent:**

- **Leuprolide Acetate** is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**Duration of therapy:**

- **Leuprolide Acetate** is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.

**LUPRODEX 3.75 mg (DEPOT)** and norethindrone acetate.

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**LUPRODEX 3.75 mg (DEPOT)** is contraindicated in women who are pregnant while receiving the drug. **LUPRODEX 3.75 mg (DEPOT)** may cause fetal harm when administered to a pregnant woman.

**Monitoring in Advanced Prostatic Cancer Patients:**

- **Color Cardiac System / Hypertension, Pulmonary embolism**
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**Precautions & Warnings:**

- **Leuprolide Acetate** is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone (GnRH) or LHRH. The analog possesses greater potency than the natural hormone.
The product has been shown to be stable for 24 hours following reconstitution. Since the product does not contain a preservative, the reconstituted product should be discarded if not used immediately.

**INDICATIONS**

In girls, subcutaneous administration of 200 to 500 times the recommended human dose, expressed on a per body weight basis, resulted in inattention, decreased activity, and local irritation at the injection site. There is no evidence that there is a clinical counterpart of this phenomenon. In early clinical trials using daily subcutaneous Leuprolide Acetate in patients with prostate cancer, doses as high as 20 mg/day for up to two years caused no adverse effects differing from those observed with the 1 mg/day dose.

**STORAGE:**

Store below 25 C. Do not freeze.

**PRESENTATION:**

Each pack of LUPRODEX™ 3.75 mg (DEPOT) is supplied as one vial containing microspheres equivalent to 3.75 mg of Leuprolide Acetate along with one ampoule of diluent for reconstitution, one disposable syringe, two needles, and two alcohol swabs.

**REFERENCES:**


Manufactured in India by:
BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27, Additional M.I.D.C.,
Ambernath (E) - 421 501

**Procedure for Reconstitution:**

**LUPRODEX™ (DEPOT)**

**3.75 mg**

Use Aseptic Technique Throughout

Do not use Sterile Water for Injection or Sodium Chloride Injection (Saline) for reconstitution in place of the recommended diluent provided with this pack.

**Use luer lock syringe with 22 gauge needle provided with this pack.**

**Fix needle in luer lock till it rotates no more.**

Withdraw 1ml of diluent from the ampoule.

**Remove plastic seal cap of vial by flicking it off.**

Inject diluent into the vial.

**Shake well the contents of vial for thorough Dispersion.**

The suspension will appear uniformly milky.

Withdraw entire contents of the vial back in the syringe.

Inject intramuscularly / subcutaneously

Discard the remainder of the diluent, the ampoule and the vial.

Visually inspect the vial. Vial should not be used if dumping or caking is evident. A thin layer of powder on the wall of the vial is considered normal. The diluent in the ampoule should appear clear.

Ensure that the fluid is at the bottom section of the ampoule (flick or tap lightly if need be).

Hold the ampoule and snap open the ampoule as shown in the picture.

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