

<b>Product name:</b>	Luprodex 3.75 mg (Depot) [Leuprolide Acetate for Injection 3.75 mg (Depot)] For Intra-muscular / Subcutaneous usage
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**Read the instruction carefully before use:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor/ health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor/ health care provider.
- Keep out of reach of children.

**What Luprodex 3.75 mg (Depot) is and what it is used for?**

LUPRODEXTM 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.

**IT IS USED FOR**

Leuprolide Acetate used to reduce levels of testosterone and estrogen circulating in the body.

*In females* it helps in the following

- Pain relief and reduction of endometriosis lesions
- Provide symptomatic relief for women close to menopause who do not desire surgery, or as an adjunct to surgery.
- Used as concomitant medication to iron therapy for improving haemoglobin level before surgical treatment in Uterine Fibroids

*In males*

- Used as an alternative treatment for Advanced Prostate Cancer when orchidectomy or estrogen administration are not indicated or not acceptable by the patient

*In children*

- Used to treat Central Precocious Puberty (CPP)

**Before you take Luprodex 3.75 mg (Depot)**

You should not take the medicine if you have

- Allergic reaction to Luprodex 3.75 mg (Depot) or similar medications.
- Abnormal vaginal bleeding that has not been diagnosed by a doctor.
- Pregnant females should not be given this medicine.

**Take special care with Luprodex 3.75 mg (Depot)**

When you take Luprodex, and if you are diabetic then check your sugar levels. If there is thinning of bones then you should tell your doctor, who will prescribe you some calcium supplements. In women, if there is unusual bleeding, then contact your doctor immediately.

**HOW TO TAKE Luprodex 3.75 mg (Depot)**

LUPRODEX™ 3.75 mg (DEPOT) is a monthly depot used for symptomatic relief for above mentioned conditions. The depot can be used as directed by your doctor and maximum up to six months.

**If you take more Luprodex 3.75 mg (Depot) than you should**

Should be watchful for any sign and symptoms that might develop and seek immediate help from doctor.

**If you forget to take Luprodex 3.75 mg (Depot)**

Contact your doctor if you miss a dose of Luprodex 3.75 mg (Depot). Doctor shall tell you when to take the next injection. Missing a dose can cause menstrual bleeding in females. In children pubertal symptoms may return.

**POSSIBLE SIDE EFFECTS**

LUPRODEX™ 3.75 mg (DEPOT) can cause undesirable side effects like hot flushes, swelling in legs, stomach upset, diarrhoea, vomiting, loss of appetite, generally unwell feeling, or bone pain or fracture as the bone density is decreased. There could be pain and swelling at the site of injection, inflammation of joint, pain in muscles, decrease in blood pressure, decrease in white blood counts.

It can cause allergic symptoms like rash, itching, breathing difficulty, etc.

For men – in prostate cancer, they may experience local pain, hot flushes, swelling in leg, difficulty in urination.

For women- mood changes, depression, etc may be present.

**HOW TO STORE Luprodex 3.75 mg (Depot)**

Store below 30°C. Do not freeze.

**FURTHER INFORMATION**

**What Luprodex 3.75 mg (Depot) contains**

**Each vial contains** (As lyophilized powder):

Leuprorelin B.P. (As acetate) ..... 3.75 mg

Excipients : Poly (D,L-lactide-co-glycolide) Biodegradable Polymer, D-Mannitol B.P.

**Ampoule of diluent for reconstitution:**

Each mL contains:

D-Mannitol B.P. .... 50mg

Water for Injection USP. .... q.s.

Other Excipients: Sodium Carboxymethyl Cellulose USP. as a suspending agent and Polysorbate-80 as a wetting agent.

**What Luprodex 3.75 mg (Depot) looks like and contents of the pack**

**Description of finished product.**

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.

**Pack Size**

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

**Signs & Symptoms of overdose**

Overdosage can cause weakness or irritation or difficulty in breathing. You should consult doctor immediately.

**When should you consult your doctor, pharmacist?**

If any adverse side effects occurs to you, if you miss a dose or if there are symptoms of overdosing then should immediately consult your doctor or pharmacist.

**Shelf-life of product**

36 months.

**The product license/ authorization holder is:**

**BHARAT SERUMS AND VACCINES LIMITED**

3rd Floor, Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai 400708 - India

Manufactured in India by:

**BHARAT SERUMS AND VACCINES LIMITED**

Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional M.I.D.C., Ambernath East- 421506, Maharashtra State – India

**For any information about this medicinal product, please contact the <local representative of the> supplier:**

**Date of Revision of PIL: 29/04/2024**