

**Lorelin® Depot Injection**  
**Leuprorelin acetate 11.25mg**  
**3-month injection for LHRH analogue**

**1. What Lorelin 11.25mg is used for?**

Leuprorelin acetate 11.25mg is a synthetic analogue of gonadotropin releasing hormone (GnRH or LHRH analogue). The analog possesses greater potency than natural hormone.

**It is used for the following indications:**

- Advanced Prostate Cancer
  - A cancer of prostate gland mostly occurring in adult males.
- Endometriosis
  - A condition resulting from the appearance of endometrial tissue outside the uterus and causing pelvic pain, especially associated with menstruation.
- Uterine Fibroids
  - These are very common non-cancerous (benign) growths that develop in the muscular wall of the uterus causing heavy bleeding, pelvic pressure/pain, frequent urination &/or constipation.

**2. Before Lorelin 11.25mg is administered to you:**

**Lorelin 11.25mg should not be used:**

- If you are known or suspected to be hypersensitive (allergic) to GnRH, GnRH agonists or any of the excipients in Lorelin.
- If you have undiagnosed vaginal bleeding.
- If you are pregnant or lactating.

**Special care should be taken with Lorelin 11.25mg:**

- It may cause impairment in fertility, which may reverse when the drug is

discontinued after continuous administration for up to 24 weeks.

- Dose related increase may cause fetal abnormalities.
- Unknown effects in breast milk.
- Not studied in patients over the age of 65 years.

**Pregnancy and Breast Feeding:**

*Pregnancy*

Lorelin 11.25mg is contraindicated in pregnant women and contraceptives are advised if use of Lorelin is indicated.

*Breast-Feeding*

Lorelin should not be used by nursing mothers.

**3. How Lorelin 11.25 is administered to you?**

**Method and routes of administration**

- The injection is prepared just before administration.
- Uniform suspension is made by mixing the powder thoroughly.
- The entire contents of the syringe should be injected intramuscularly.
- It should not be injected intravenous because it might cause thrombosis.

**Dosage:**

Lorelin depot must be administered under supervision of a physician:

*Prostate Cancer*

Lorelin depot 11.25mg is given once in 3 months for palliative treatment of advanced prostate cancer. It can be used till patient gets benefit.

*Endometriosis*

The recommended duration of treatment with Lorelin depot 3 monthly injection alone or in combination with norethindrone acetate is six months. The choice of Lorelin depot alone or in combination therapy for initial management of

signs & symptoms of endometriosis should be made by healthcare professional in consultation with the patient.

If the symptoms of endometriosis recur after a course of therapy, retreatment with a six month course of Lorelin & norethindrone acetate 5mg daily may be considered. Retreatment beyond six month should be done after assuring bone density within normal limits.

#### *Uterine Leiomyomata*

The recommended dose of Lorelin depot 11.25mg once in 3 months. The symptoms associated with uterine leiomyomata will recur following discontinuation of therapy. If additional treatment with Lorelin depot is contemplated, bone density should be assessed prior to initiation of therapy to ensure values within normal limits.

#### **Lorelin post administration effects:**

During the early phase of therapy, sex steroids temporarily rise above baseline because of the physiologic effect of the drug. Therefore, an increase in clinical signs and symptoms may be observed during the initial days of therapy, but these will dissipate with continued therapy.

#### **4. Possible Side Effects**

Like all medicines, Lorelin 11.25mg has side effects.

- Body: Body odor, flu syndrome, injection site reactions
- Cardiovascular system: Palpitations, blackout feeling, increased heart rate
- Gastrointestinal system: Appetite changes, dry mouth, thirst
- Endocrine system: Androgen-like effects
- Blood and lymphatic system: Bruising and swelling of lymph glands
- Nervous system: Anxiety, insomnia/sleep disorder, delusions, memory disorder, personality disorder
- Respiratory system: Flu-like symptoms

- Skin: Alopecia, increased hair growth, nail disorder
- Special senses: Pink eye, taste perversion
- Urogenital system: Painful urination, difficult lactation, menstrual disorder

After Lorelin depot 11.25mg, vertebral bone density measured by DEXA scan decreased compared with baseline by an average of 3.0% & 2.8% at six months.

#### **5. Storing Lorelin 11.25mg**

Store at 25 deg C (77 deg F) Room temperature in dry place

Shelf life – 3 years

#### **6. Further information**

The vial of Lorelin depot contains Leuprorelin acetate 11.25mg, polylactic acid 99.3mg and D-mannitol 19.45mg.

The accompanying ampoule of diluent contains carboxymethylcellulose sodium 5mg, D-mannitol 50.0 mg, polysorbate 80 (1mg), water for injection.

Each vial contains sterile lyophilized microspheres which are Leuprorelin acetate incorporated in biodegradable polymer of polylactic acid. When mixed with 1.0 ml of the diluent Lorelin depot is administered as a single IM injection every 3 months.

Manufactured by: Dongkook Pharmaceutical, KOREA

Imported & marketed by:

