LUPRORIN DEPOT INJECTION:

COMPOSITION: Luprolide Acetate for Injection (Depot) 3.75 mg For I.M./S.C. Use. Single Dose Vial. INDICATIONS 1. Endometriosis2. Uterine Leiomyomata (fibroids)-Reduction of Myoma Nucleus and Improvement of Symptom in Uterine Myoma accompanied with Hypermenorrhea, Hypogastriumache, Lumbago, Anemia3. Central Precocious Puberty4. Prostatic cancer.DOSAGE AND ADMINISTRATION1. In case of endometriosis, Usually, administer 3.75 mg of this drug as suspended in Leuprolide acetate Intramuscularly/subcutaneously to an adult patient once per 4 weeks. The initial administration shall be made on the 1st-5thday after menstruation begins duration of initial treatment should be limited to 6 months.2. In case of uterine myoma; Usually, administer 1 injection Intramuscularly/subcutaneously to an adult patient once per 4weeks.The initial administration shall be made on the 1st-5th day after menstruation begins the bone mineral density should be assested prior to initation of therapy to ensure that value are within normal limits.3. In case of central precocious puberty, Usually, administer 30 µg/kg body weight of this drug as suspended in Leuprolide acetate Intramuscularly/subcutaneously to an adult patient once per 4 weeks. Such dose can be also increased upto 90 µg/kg depending upon the symptoms.4. In case of prostatic cancer, premenopausal breast cancer, usually, administer 3.75 mg, Intramuscularly/subcutaneously to an adult patient once a month. CONTRAINDICATIONS1. Hypersensitivity to GnRH, GnRH agonist analogues or any of the excipients in LUPRORIN DEPOT INJ..2. Undiagnosed abnormal vaginal bleeding.3. LUPRORIN DEPOT INJ. is contraindicated in women who are or may become pregnant while receiving the drug. LUPRORINDEPOT INJ. may cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.4. Use in women who are breast-feeding. 5. Norethindrone acetate is contraindicated in women with the following conditions:Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions, Markedly impaired liver function or liver disease,Known or suspected carcinoma of the breast. WARNINGS & PRECAUTIONS Safe use of Leuprolide acetate or Norethindrone acetate in pregnancy has not been established clinically. Before starting treatment with LUPRORIN DEPOT INJ., pregnancy must be excluded. When used monthly at the recommended dose, LUPRORIN DEPOT INJ. usually inhibits ovulation and stops menstruation. 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. Symptoms consistent with an anaphylactoid or asthmatic process have been rarely reported post-marketing.Patient Information leaflet is included with the product. Patients should be aware of the following information:1. Since menstruation usually stops with effective doses of LUPRORIN DEPOT INJ., the patient should notify her physician if regular menstruation persists. Patients missing successive doses of LUPRORIN DEPOT INJ. may experience breakthrough bleeding.2. Patients should not use LUPRORIN DEPOT INJ. if they are pregnant, breast feeding, ave undiagnosed abnormal vaginal bleeding, or are allergic to any of the ingredients in LUPRORIN DEPOT INJ..3. Safe use of the drug in pregnancy has not been established clinically. Therefore, a non-hormonal method of contraception should be used during treatment. Patients should be advised that if they miss successive doses of LUPRORIN DEPOT INJ.,breakthrough bleeding or ovulation may occur with the potential for conception. If a patient becomes pregnant during treatment, she should discontinue treatment and consult her physician.4. Adverse events occurring in clinical studies with LUPRORIN DEPOT INJ. that are associated with hypoestrogenism include:hot flashes, headaches, emotional lability, decreased libido, acne, myalgia, reduction in breast size, and vaginal dryness. Estrogen levels returned to normal after treatment was discontinued.5. Patients should be counseled on the possibility of the development or worsening of depression and the occurrence of memorydisorders.6. The induced hypoestrogenic state also results in a loss in bone density over the course of treatment, some of which may not be reversible. For a period up to six months, this bone loss should not be clinically significant. PREGNANCY, TERATOGENIC EFFECTS PREGANACY AND LACTATION :Pregnancy Category XNursing Mothers: It is not known whether LUPRORIN DEPOT INJ. is excreted in human milk. Because many drugs are excreted in human milk, and because the effects of LUPRORIN DEPOT INJ. on lactation. and/or the breast-fed child have not been determined, LUPRORIN DEPOT INJ. should not be used by nursing mothers. ADVERSE REACTIONS: During postmarketing surveillance, the following adverse events were reported. Like other drugs in this class, mood swings,including depression, have been reported. There have been rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of depression or other psychiatric illness. Patients should be counseled on the possibility of development or worsening of depression during treatment with LUPRORIN DEPOT INJ. Symptoms consistent with an anaphylactoid or asthmatic process have been rarely reported. Rash, urticaria, and photosensitivity reactions have also been reported.Localized reactions including induration and abscess have been reported at the site of injection. Symptoms consistent with fibromyalgia (eg: joint and muscle pain, headaches, sleep disorder, gastrointestinal distress, and shortness of breath) have been reported individually and collectively. Other events reported are:Cardiovascular System-Hypotension, Pulmonary embolism; Hemic and Lymphatic System-Decreased WBC; Central/PeripheralNervous System-Peripheral neuropathy, Spinal fracture/paralysis; Musculoskeletal System-Tenosynovitis-like symptoms;Urogenital System-Prostate pain.Pituitary apoplexy: During post-marketing surveillance, rare cases of pituitary apoplexy (a clinical syndrome secondary to infarction of the pituitary gland) have been reported after the administration of gonadotropin-releasing hormone agonists. OVERDOSAGE: In rats subcutaneous administration of 250 to 500 times the recommended human dose, expressed on a per body weight basis,resulted in dyspnea, 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 LUPRORIN DEPOT INJ. 3.75 mg 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. (For details, please refer full prescribing information)

(For the use of a registered medical practitioner or hospital or laboratory only)