LUTERONE DEPOT

Ampoule

Composition

Luterone 250 Depot
Each ampoule of 1 ml contains Hydroxyprogesterone caproate 250 mg in a sterile oily solution.

Luterone 500 Depot
Each ampoule of 2 ml contains Hydroxyprogesterone caproate 500 mg in a sterile oily solution.

Action

A long-acting progestin, Luterone Depot has duration of action lasting 9-17 days. Luterone Depot prevents follicular maturation and ovulation by inhibiting the secretion of pituitary gonadotropins. Luterone Depot transforms proliferative endometrium into secretory endometrium. Luterone Depot inhibits spontaneous uterine contraction.

Indications

- Amenorrhea (primary and secondary).
- Functional uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.
- Production of secretory endometrium and desquamation. Adenocarcinoma of uterine corpus in advanced stage (stage III or IV).
- Test for endogenous estrogen production.

Contraindications

- Known hypersensitivity to Hydroxyprogesterone caproate or other progestins.
- Use during the first 4 months of pregnancy is contraindicated.
- Hydroxyprogesterone caproate is contraindicated in patients who suffer from thrombophlebitis, cerebral hemorrhage, impaired liver function, thromboembolic disorders, miscarriage, suspected or incomplete abortion, carcinoma of the breast or reproductive organs, undiagnosed vaginal bleeding.
- Hydroxyprogesterone caproate should not be used as a diagnostic test for suspected pregnancy and a history of herpes gestationis.

Warnings

There is no adequate evidence to show that Hydroxyprogesterone caproate is effective in preventing habitual abortion or threatened abortion, and is no longer recommended for such use.

Patients, who suffer from hepatic disorders, incomplete abortion, pregnancy, or abnormal vaginal bleeding, should not use this drug.
If sudden, partial or complete loss of vision occurs, or if there is sudden onset of proptosis, diplopia or migraine, discontinue use of this drug.

The following symptoms are occasionally associated with Hydroxyprogesterone caproate treatment: thrombophlebitis, cerebrovascular disorders, retinal thrombosis, and pulmonary embolism. If these occur or are suspected, discontinue use of the drug immediately.

Pregnancy
Category D
Use during pregnancy is not recommended.

There is evidence of potential harm to the fetus when this drug is given during the first 4 months of pregnancy, and it is therefore strictly contraindicated for use during this period. If the patient is nevertheless exposed to progestational therapy during the first 4 months of pregnancy or if she becomes pregnant while taking this drug, she should be advised of the potential risks to the fetus - genital abnormalities in male and female, a risk of hypospadias in the male fetus and masculinization of the female fetus.

Nursing Mothers
Progestins are detected in breast milk. The effect on the infant has not been determined.

Adverse Reactions
Following the administration of Hydroxyprogesterone caproate, changes in the pattern of vaginal bleeding occur, including irregular cycle time, spotting, breakthrough bleeding, or complete lack of bleeding.

The following side effects occur less frequently: severe or sudden headaches, sudden loss of coordination, pains in the chest, pains in the groin or leg, sudden unexplained shortness of breath, sudden slurred speech, sudden changes in vision, weakness, numbness or pain in the arm or leg, galactorrhoea, hepatitis, gallbladder obstruction, skin rash or itching, mental depression, neuro-ocular lesions, bulging eyes, double vision, loss of vision (gradual, partial or complete), changes in appetite, changes in weight, edema, acne, fever, increased body and facial hair, increased breast tenderness, melasma or chloasma (brown blotchy spots on exposed skin), nausea, some loss of scalp hair, trouble in sleeping.

Precautions
The patient should undergo physical examination prior to initiation of treatment. This examination should include the breasts and pelvic organs, and a Papanicolaou smear.
Fluid retention during therapy may occur. Therefore, conditions like epilepsy, migraine, asthma, cardiac or renal dysfunction require careful observation.

Patients who have a history of psychic depression must be monitored. Discontinue use of drug if depression recurs to a serious degree.

Diagnostic Interference
Laboratory test results of hepatic coagulation and endocrine functions may be affected in patients receiving this drug. Pregnanediol determination may be altered.

Dosage and Administration
Amenorrhea (primary and secondary) or Functional Uterine Bleeding
375 mg administered intramuscularly at any time during the menstrual cycle. After 4 days of desquamation, or 21 days after injection if there is no bleeding, start cyclic therapy (see cyclic therapy schedule below). Repeat cyclic therapy schedule every 4 weeks. Stop after 4 cycles. To determine onset of normal cyclic function, observe patient 2 or 3 cycles after cessation of therapy.

Production of Secretory Endometrium and Desquamation
For patients not on estrogen therapy, start cyclic therapy (see cyclic therapy schedule below). Repeat every 4 weeks until no longer required. Note that menstruation may not occur until estrogen has been given for several months, if estrogen deficiency has been prolonged.

Cyclic Therapy Schedule
20 mg estradiol valerate injection I.M. on day 1 of the cycle, followed by 250 mg injection of Luterone Depot and 5 mg estradiol valerate injection on day 15 of the cycle.

Adenocarcinoma of Uterine Corpus
In the treatment of advanced (stage III or IV) adenocarcinoma of the uterine corpus, administer 1 gram injections, repeating up to 7 times a week. Stop when relapse occurs, or after 12 weeks of therapy if there is no satisfactory result.

Test for Endogenous Estrogen Production
Administer a single injection of 250 mg. Repeat, if necessary, 4 weeks later. Stop after the second injection. In the non-pregnant patient with responsive endometrium, bleeding 7-14 days after injection indicates endogenous estrogen.

Pharmaceutical Precautions

Store below 30 ºC, preferably between 15 ºC and 30 ºC.
Protect from freezing, in case freezing occurs, warm the ampoule with hot water until contents redissolve.

Presentation

Luterone Depot 250 Injection
Box of 5 ampoules.

Luterone Depot 500 Injection
Box of 1 ampoule.