Femolife®

Hydroxyprogesterone (caproate)
Injection
Ampoule 250 mg/1ml

Category
Progestational agent; diagnostic aid

Indications
Amenorrhea, dysfunctional uterine bleeding, induction of menses, test for endogenous estrogen production and production of a secretory endometrium and desquamation

Drug interaction
Hepatic enzyme inducing medications, such as Carbamazepine, Phenobarbital, Phenytoin, Rifabutin or Rifampin

Contraindications
Except under special circumstances, these medications should not be used when the following medical problems exist:
- Allergy to peanuts
- Breast malignancies or tumors
- Hepatic disease, including benign or malignant liver tumors
- Hypersensitivity to progestins
- Pregnancy
- Thrombophlebitis or thromboembolic disease
- Urinary tract bleeding
- Uterine or genital bleeding

Risk-benefit should be considered when the following medical problems exist:
- Asthma
- Cardiac insufficiency
- Epilepsy
- Hypertension
- Migraine headaches
- Renal dysfunction
- CNS disorders, such as depression or convulsions
- Diabetes mellitus
- Hepatic disease or dysfunction
- History of Hyperlipidemia
- Significant risk factors for low bone mineral content
- Thromboembolic disorders, including cerebrovascular disease
- Pulmonary embolism and retinal thrombosis
- Thrombophlebitis

Precautions
Regular visits to health care professional
Checking with doctor immediately if uterine bleeding (spotting or breakthrough menstrual bleeding) continues longer than 3 months or if menstruation is delayed by 45 days
Contacting doctor immediately if pregnancy is suspected or a menstrual period is missed.

Pregnancy/ Breast feeding
FDA Pregnancy Category D
Use is generally not recommended during pregnancy, unless prescribed in the treatment of female infertility due to progesterone deficiency. Hydroxyprogesterone and progesterone have been used to prevent habitual or threatened abortion within the first few months of pregnancy. There are no adequate and well-controlled studies in Humans to document that such use are effective during the first 4 months of pregnancy in preventing miscarriage.

Progestins are distributed into breast milk and may increase or decrease quantity or quality or have no effect on breast milk. The effect on the nursing infant has not been determined for many progestins. Progestins used in very high doses are not recommended for use by nursing mothers. ¹

Side/adverse effects

Those indicating need for medical attention

More frequent:
Amenorrhea; breakthrough menstrual bleeding or metromenorrhagia medium to heavy uterine bleeding between regular monthly periods; hyperglycemia; menorrhagia; spotting; coughing

Note: For all progestins, if abnormal uterine bleeding is persistent (longer than 10 days at a time) or recurring heavier than normal menses occurring longer than 10 months after beginning therapy or more often than monthly, malignancy should be considered as a cause of the bleeding.

Less frequent:
Galactorrhea; mental depression; skin rash

Rare:
Adrenal suppression or insufficiency or hypotension; Cushing's syndrome; thromboembolism or thrombus formation

Those indicating need for medical attention only if they continue or are bothersome

More frequent:
Abdominal pain or cramping; diarrhea; dizziness; drowsiness; edema; fatigue; headache; mood changes; nausea; nervousness; ovarian enlargement or ovarian cyst formation; pain, redness, or skin irritation at the site of injection or implantation; unusual tiredness or weakness; unusual or rapid weight gain; vomiting; dyspnoea

Less frequent:
Acne; breast pain or tenderness; hot flashes; insomnia; libido decrease; loss or gain of body, facial, or scalp hair; melasma ¹,²

Dosage and Administrations

Usual adult dose

Amenorrhea or Dysfunctional uterine bleeding; Intramuscular, 375 mg
Estrogen production (endogenous) diagnosis: Intramuscular, 125 to 250 mg given on Day 10 of the menstrual cycle, repeated every seven days until suppression is no longer desired.
Note: Withdrawal bleeding usually occurs within three to seven days after discontinuing therapy.

**Usual pediatric dose**

Safety and efficacy have not been established.

**Storage, strength(s) and packaging**

Store between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing.

Femolife® ampoule is supplied in packs of 10 ampoules with a leaflet inside a box. Each ampoule (1ml) contains 250 mg hydroxy progesterone caproate.

Manufactured by Aburaihan Pharmaceutical Co.

**References:**

1. USPDI 2010

2. MARTINDALE: the complete drug reference 2010