CETROLIX-PFS(Cetrorelix Acetate Injection 0.25 mg/0.5 ml)(For subcutaneous use only)

Composition: Each 0.5 ml contains: Cetrorelix Acetate eq. to Cetrorelix....0.25 mg Water for Injections IP.Q.S. to 0.5 ml **Indications** indicated for the prevention of premature ovulation in patients undergoing a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques. **Dosage and administration:** CETROLIX-PFS should be administered subcutaneously (into lower abdominal wall) once daily. Ovarian stimulation therapy with gonadotropins (FSH, Human menopausal gonadotropin (hMG)) is started on cycle Day 2 or 3 and dose of gonadotropins should be adjusted according to individual response. Cetrorelix dose of 0.25 mg is administered subcutaneously once daily on either ovarian stimulation day 5 (morning or evening) or day 6 (morning) and continued once daily until the day of human chorionic gonadotropin (hCG) administration. When assessment by ultrasound shows a sufficient number of follicles of adequate size, human chorionic gonadotropin (hCG) is administered to induce ovulation and final maturation of the oocytes. No hCG should be administered if the ovaries show an excessive response to the treatment with gonadotropins to reduce the chance of developing ovarian hyperstimulation syndrome (OHSS). **Method of administration.** CETROLIX-PFS is for subcutaneous injection into the lower abdominal wall. The injection site should be varied daily when being used in the multiple dose regimens. **Contraindications:** Hypersensitivity to cetrorelix acetate, extrinsic peptide hormones or mannitol. Known hypersensitivity to GnRH or any other GnRH analogs. Known or suspected pregnancy, and lactation. Patients with moderate and severe renal or hepatic impairment. **Warnings and precautions:** Before starting treatment with Cetrorelix, pregnancy must be excluded. Caution is advised in patients with hypersensitivity to GnRH. Special care should be taken in women with signs and symptoms of active allergic conditions or known history of allergic predisposition. Treatment with CETROLIX-PFS is not advised in women with severe allergic conditions. During or following ovarian stimulation, an ovarian hyperstimulation syndrome can occur. This event must be considered as an intrinsic risk of the stimulation procedure with gonadotropins. An ovarian hyperstimulation syndrome should be treated symptomatically e.g. with rest, intravenous electrolytes/colloids and heparin therapy. During stimulation with human menopausal gonadotropin, Cetrorelix acetate had no notable effects on hormone levels aside from inhibition of LH surges. **Pregnancy and lactation:** The use of cetrorelix is contraindicated in pregnant women. The fetal resorption is observed in animal studies. Therefore, this drug should not be administered to pregnant women. It is not known whether cetrorelix is excreted in human milk. Because many drugs are excreted in human milk, the use of cetrorelix is not recommended in nursing mothers. **Adverse drug reactions:** Local reactions at the injection site (e.g., erythema, redness, itching, bruising, swelling and pruritus) can occur. Usually transient in nature and of mild intensity. Nausea and headache. Uncommon cases of hypersensitivity reactions including pseudo-allergic/anaphylactoid reactions have also been reported. Mild to moderate ovarian hyperstimulation syndrome can occur, which is an intrinsic risk of the stimulation procedure. Uncommonly severe ovarian hyperstimulation syndrome) can occur. Congenital Anomalies: The use of cetrorelix is contraindicated in pregnant women. The causal relationship between the reported anomalies and cetrorelix is unknown. Multiple factors, genetic and others (including, but not limited to ICSI, IVF, gonadotropins, and progesterone) make causal attribution difficult to study. Last updated on 3/8/2020. For further information, please refer full prescribing information.

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