Prescribing information for Zivafert ▼ PFS (Human chorionic gonadotropin (HCG) 5000 IU),

Presentation: Zivafert PFS 5000 IU is a Powder and solvent for solution for injection. Powder in vial is white to almost white lyophilized powder. The solvent in the pre-filled syringe is (0.9% sodium chloride) and is a clear and colourless solution. Each vial of powder contains: HCG 5000 IU, produced from human urine.

Indication: In anovulatory or oligo-ovulatory women to trigger ovulation and luteinisation induction after stimulation of follicle growth. For Assisted Reproductive Technology (ART) program such as in vitro fertilisation IVF): triggering of final follicular maturation and luteinisation after stimulation of follicle growth.

Dosage and administration: The treatment should only be initiated by a physician experienced in treating infertility. Anovulatory or oligo-ovulatory women: One vial (5000 IU) or two vials (10000 IU) of Zivafert PFS are administered 24 to 48 hours after optimal stimulation of follicular growth are achieved. The patient is recommended to have coitus on the day of, and the day after, Zivafert PFS injection. For ART program such as IVF: One vial (5 000 IU) or two vials (10000 IU) of Zivafert PFS are administered 24 to 48 hours after the last administration of an FSH- or hMG preparation.

Contraindications: Hypersensitivity to active substance or any of the excipients. Uncontrolled non-gonadal endocrinopathies (e.g., thyroid disorders); breast, uterine and ovarian tumours; abnormal (not menstrual) vaginal bleeding of unknown aetiology. Zivafert PFS should not be used when an effective response cannot be obtained, such as in cases of primary ovarian failure and malformations and tumours incompatible with pregnancy.

Undesirable effects: Reactions at the site of injection which are usually mild and transient. The most serious adverse reaction is ovarian hyperstimulation syndrome (OHSS). Local hypersensitivity reaction, abdominal pain, nausea, vomiting and diarrhoea. Bruising, pain, redness, swelling and itching at the injection site. Oedema, headache, mood changes, painful breasts, ovarian cysts. (Refer to Summary of Product Characteristics (SPC) for complete list of adverse reactions).

Precautions: Following administration, Zivafert PFS may interfere for up to ten days with the immunological determination of serum or urinary hCG, potentially leading to a false positive pregnancy test. Hypersensitivity reactions, ovarian torsion ectopic pregnancy: (Early ultrasound confirmation that a pregnancy is intrauterine is important), multi-foetal gestation and birth and abortion: The parents should be advised of the potential risks of multiple pregnancies before starting treatment. The incidence of congenital malformations after ART may be higher than after spontaneous conceptions. Thromboembolic events, both in association with and separate from OHSS, have been reported following treatment with gonadotropins, including Zivafert PFS. There have been reports of reproductive neoplasms in women who have undergone multiple drug regimens for infertility treatment. The effect of gonadotrophins on the development of neoplasms in infertile women has not yet been established.

To reduce the risk of OHSS, ultrasonographic assessments of follicular development should be performed prior to treatment and at regular intervals during treatment.

Interactions: HCG can cross-react in the radioimmunoassay of gonadotropins, especially luteinizing hormone. Physicians should make the laboratory aware of patients on hCG if gonadotropin levels are requested.

Pharmaceutical Precautions: Do not store above 25°C. Keep the vial and solvent in the prefilled syringe in the original package to protect the medicine from the light.

Legal Category: POM.

Marketing Authorisation Numbers: Zivafert PFS 5000 IU – PLGB 21039/0072 - £45.

Marketing Authorisation Holder: IBSA Farmaceutici Italia S.r.l. Via Martiri di Cefalonia, 26900 Lodi, Italy.

Distributor in UK: IBSA Pharma Ltd., 4 – 6 Colonial Business Park, Colonial Way, Watford WD24 4PR, UK.

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