MyFSH®

Urofollitropin for Injection BP 75 IU / 150 IU (Lyophilized)
Highly Purified; For IM / SC use only

Therapeutic indications: For the stimulation of follicular recruitment, development of and induction of ovulation in women with hypothalamic pituitary dysfunction, presented as either oligomenorrhea or amenorrhea. Classified as WHO group II patients, women with polycystic ovarian syndrome who have failed to respond or conceive following clomiphene citrate therapy also belong to and form the major part of this group.

Dosage and Administration: MyFSH® may be administered as subcutaneous or intramuscular injection. Regimen commences at MyFSH® 75 llJ - 150 IU daily. The dose may then be increased or decreased by 37.5 IU (up to 75 IU) at 7 or 14 day intervals, if necessary, to obtain an adequate response. MyFSH® treatment should be tailored to the individual patients' response. Treatment per course should not generally exceed 14 days.

Warning and Precautions: MyFSH® should be administered with precaution in patients of possibility of OHSS which may result in fatality, significant ovarian enlargement, withhold the administration of MyFSH® in case OHSS develops prior to hCG administration. Follow up of PCOS patients for a period of two weeks after FSH treatment to observe the occurrence of OHSS; ectopic pregnancy or birth defects have been reported very rarely; diminished response to the FSH- hCG treatment in patients with hyperprolactinemia. **Contraindications:** Hypersensitivity to the purified FSH or any other content of MyFSH®, high FSH level indicating primary ovarian failure, an organic intracranial lesion such as pituitary tumor, uncontrolled case of thyroid and adrenal dysfunction, cases of infertility other than anovutation, abnormal bleeding due to undetermined origin, an ovarian cysts or enlargement not due to PCOS and pregnant women.

Adverse Reactions: Headache, pain, rash and even inflammation at the site of injection, brest tenderness, mild to moderate ovarian enlargement or ovarian cysts formation, GI tract disturbances such as nausea and vomiting, diarrhea, bloating, abdominal, pain and abdominal cramps, dry skin and hair loss, ovarian over stimulation and OHSS.

Dosage Forms and Strengths: Each MyFSH® 75 IU/150 IU vial of sterile freeze-dried product contains Urofollitropin (FSH) BP 75 IU/150 IU; Mannitol IP q.s.; Potassium Dihydrogen Phosphate BP q.s.; Dipotassium Hydrogen Phosphate BP q.s.

Storage: Store between 2^{0} - 8°C. Do not freeze. Protect from light.

Manufactured by: Sanzyme (P) Ltd. Plot No. 8, Sy. No. 542, Phase-II, Alexandria Knowledge Park, Koltur (V), Shameerpet (M), RR District-500 078, Telangana State, India.

Marketed by: Mylan Pharmaceuticals Private Limited Plot No. 1-A/2, MIDC, Industrial Estate, Taloja, Panvel, Raigad (Dist), Maharashtra - 410 208, India.

Abbreviated Prescribing Information Version 12/2016.

Please refer to the full Prescribing Information before prescribing MyFSH®, available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087.