

MyHCG®

Chorionic Gonadotrophin Injection IP 2000 IU / 5000 IU / 10000 IU(Lyophilized)

Highly Purified; For IM / SC use only

Therapeutic indications:

Anovulatory infertility

Prepubertal cryptorchidism not due to anatomical obstruction

Selected cases of Hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

Dosage and Administration:

MyHCG® is given by either subcutaneous or intramuscular injections only, after addition of the solvent (provided in the carton) to the sterile highly purified substance. Inject the reconstituted solution immediately

1. **Anovulatory infertility:** Usually one injection of MyFSH® 5000 IU / 10000 IU is given one day following the last dose of menotrophins (given to create prior stimulation of follicular maturation and endometrial proliferation). Up to 3 repeat injections of 5000 IU each may be given within the following 9 days to prevent insufficiency of the corpus luteum.
2. **Selected cases of hypogonadotropic hypogonadism in males:**
 - a. 500 IU to 1000 IU 3 times a week for 3 weeks, followed by the same dose twice week for 3 weeks.
 - b. 4000 IU 3 times weekly for 6 to 9 months, following which the dosage may be reduced to 2000 IU 3 times weekly for an additional 3 months.
3. **Prepubertal cryptorchidism not due to anatomical obstruction. Therapy is usually instituted in children between the ages of 4 and 9.**
 - a. 4000 IU 3 times weekly for 3 weeks.
 - b. 5000 IU every second day for 4 injections.
 - c. 15 injections for 500 IU to 1000 IU over a period of 6 weeks.
 - d. 500 IU units 3 times weekly for 4 to 6 weeks. If this course of treatment is not successful, another series is begun 1 month later, giving 1000 IU per injection.

Warning and Precautions: Induction of androgen secretion by MyFSH® may induce precocious puberty in patients treated for cryptorchidism. Therapy should be discontinued if signs of precocious puberty occur. Since androgens may cause fluid retention, MyFSH® should be use with caution in patients with cardiac or renal disease, epilepsy, migraine or asthma. **Contraindications:** Precocious puberty, prostatic carcinoma or other androgen dependent neoplasm. Prior allergic reactions to HP hCG.

Adverse Reactions: Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia, pain at site of injection, skin rashes.

Dosage Forms and Strengths: MyFSH® is available as Combipack of 1 vial of either 2000 IU or 5000 IU with 1 ampoule containing 1 ml of sodium Chloride Injection IP (0.9% w/v).

Storage: Store between 2^o - 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.