**MyHMG®**
Menotropin for Injection IP 75 / 150 IU (Lyophilized)
Highly Purified; For IM / SC use only

**Therapeutic indications:** Follicular stimulation in females with anovulatory infertility and Stimulation of spermatogenesis in males with oligospermia.

**Dosage and Administration:** MyHMG® is given by subcutaneous or intramuscular injection. Reconstitute with 1 ml of Sodium Chloride Injection IP (0.9% w/v) provided with pack. Use immediately after reconstitution.

In Females: Two dosage schedules may be employed.

**Schedule 1: Alternative day therapy**
3 equal MyHMG®injections are given on alternate days in the first half (proliferative phase) of the menstrual cycle. This is followed by a single dose of 5000 IU hCG given one week after the first injection of MyHMG®provided the clinical and biochemical responses are adequate and not excessive.

**Schedule 2: Daily therapy**
Daily injection of MyHMG® is given until an adequate response is achieved. This is judged on the basis of daily estrogen determinations or sonography. In the absence of a response the dose of MyHMG® may be increased or the course may have to be abandoned. A single injection of 5000 IU - 10000 IU of hCG is administered 24 - 48 hrs after last dose of MyHMG®.

**In Males**
In the treatment of oligospermia, 1 vial of MyHMG®is given 3 times a week in combination with hCG 2000 IU, 2-3 times a week. The combined therapy should continue for at least 4 months. In men, elevated FSH levels are indicative of primary testicular failure. Such patients are unresponsive to hMG / hCG therapy.

**Special warnings and precautions for use:** It is a potent gonadotropic substance capable of causing mild to moderate adverse reactions in women like ovarian hyperstimulation, pulmonary and vascular complications, multiple pregnancies and hypersensitivity/anaphylactic reactions. Careful attention should be given to diagnosis in the selection of candidates for hMG therapy. **Contraindications:** A high FSH level indicating primary ovarian failure, uncontrolled thyroid and adrenal dysfunction, an organic intracranial lesion such as a pituitary tumor, the presence of any cause of infertility other than anovulation unless they are candidates for IVF, abnormal bleeding of undetermined origin, ovarian cysts or enlargement not due to polycystic ovarian syndrome, prior hypersensitivity to hMG and pregnancy.

**Side Effects:** Sensitivity reactions, ovarian hyperstimulation with enlargement or rupture and multiple pregnancies have been reported. Pulmonary and vascular complications, hemoperitoneum, adnexal torsion (as a complication of ovarian enlargement), mild to moderate ovarian enlargement, ovarian cysts, abdominal pain, sensitivity to menotropin (febrile reactions suggestive of allergic response and flu like symptoms), gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal cramps, bloating), pain, rash, swelling and/or irritation at the site of injection, body rashes, dizziness, tachycardia, dyspnea, tachypnea.

**Dosage Forms and Strengths:** MyHMG® is available as combipack of 1 vial either 75 IU or 150 IU with 1 ampoule containing 1 ml of sodium chloride injection IP (0.9% w/v).

**Storage:** Store between 2° - 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 MyHMG®, available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087