MENOTAS 75/150

(MENOTROPIN FOR INJECTION IP 75/150 IU) Composition Each vial contains MENOTROPIN IP equivalent to activity of Follicle Stimulating Hormone 75 IU/150IU and Luteinising Hormone 75 IU/150IU; Excipients: Q.S. Reconstitute with 1 ml of Sodium Chloride Injection IP (0.9% w/v) provided in this pack. Indication: Women:- Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate.- Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART). Men:- for hypogonadotrophic hypogonadism in men. It may be given in combination with human chorionic Gonadotropins for the stimulation of spermatogenesis. Patients with primary testicular failure are usually unresponsive. Dosage Anovulatory infertility: The dosage and schedule of treatment must be determined according to the needs of each patient. Response is monitored by studying the patients serum estradiol levels and vaginal ultrasound visualization of follicles. Menotropin for injection 75 to 150 IU/day by intramuscular injection may be given daily which should be maintained for 7 days, and gradually adjusted if necessary until an adequate response is achieved, followed after 1 day by human chorionic Gonadotropins. In menstruating patients, treatment should be started on the 4th/5th day of the menstrual cycle. The treatment course should be abandoned if no response is seen in 3 weeks. Once adequate follicular development is evident, administration of Menotropin is stopped, and ovulation may then be induced by administering human chorionic Gonadotropins (hCG) at a dose of 5000 - 10000 IU. The administration of hCG must be withheld in cases where the ovaries are abnormally enlarged on the last day of therapy. This should reduce the chance of developing ovarian hyperstimulation syndrome (OHSS). Assisted Reproductive Technologies: The recommended initial dose of Menotropin for injection for patients who have received a GnRH agonist for pituitary suppressions: 150-300 IU daily for at least the first 5 days of treatment. Based on clinical monitoring (including serum estradiol levels and vaginal ultrasound results) subsequent dosing should be adjusted according to individual patient response. Adjustments in dose should not be made more frequently than once every two days and should not exceed 150IU per adjustment. The maximum daily dose of Menotropin for injection given should not exceed 450 IU. Once adequate follicular development is evident, hCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. The administration of hCG must be withheld in cases where the ovaries are abnormally enlarged on the last day of therapy. This should reduce the chance of developing OHSS. Hypogonadotrophic hypogonadism in men : Spermatogenesis is stimulated with chorionic Gonadotropins (1000 - 2000 IU two to three times a week) and then Menotropin for injection is given in a dose of 75 or 150 IU two or three times weekly. Treatment should be continued for at least 3 or 4 months. Method of administration & Directions for Reconstitution: Reconstitute with 1mlof Sodium Chloride Injection I.P.(0.9% w/v) provided. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Use immediately after reconstitution, administer by intramuscular or subcutaneous injection. Do not use the reconstituted solution if any visible particle is seen. Any unused solution should be discarded. Contraindications: Men and Women: contraindicated in men and women with tumours of the pituitary or hypothalamic glands or hypersensitivity to the active substance. Men: Tumours in the testes, prostate carcinoma Women: Ovarian, uterine or mammary carcinoma, pregnancy and lactation, gynaecological haemorrhage of unknown aetiology & ovarian cysts or enlarged ovaries not due to polycystic ovarian disease, primary ovarian failure,uncontrolled thyroid and adrenal dysfunction, organic intracranial lesion such as a pituitary tumor,sex hormone dependent tumors of the reproductive organs, fibroid uterus & tubal occlusion. Warnings and precautions: Mild to moderate ovarian enlargement,it generally regresses without treatment. OHSS: the lowest dose and careful monitoring can minimize the risk of overstimulation. Multiple Pregnancies, ectopic Pregnancy ,spontaneous Abortion, prevalence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. In women with generally recognized risk factors for thromboembolic events, such as personal or family history, treatment with gonadotrophins may further increase the risk. Pregnancy and lactation: Menotropin should not be given during pregnancy. It is not known whether this drug is excreted in human milk; caution should be exercised if Menotropin are administered to a nursing woman. Adverse drug reactions (ADR): abdominal pain, abdominal cramps, headache, abdominal distension, and injection site pain and reaction, Ovarian Hyperstimulation Syndrome OHSS.

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