MENOTAS XP 600 IU / 1200 IU (MENOTROPIN INJECTION 600 IU/ml) Composition:

Each ml contains: Menotropin IP (Highly Purified) equivalent to activity of Luteinizing Hormone 600 IU, Follicle Stimulating Hormone 600 IU ,Benzyl Alcohol IP 1.0 % w/v, Water for Injections IP Q.S. **Indication:** for the treatment of female and male infertility in the following conditions: 1.Anovulation , including Polycystic Ovarian Disease (PCOD), in women who have been unresponsive to the treatment with Clomiphene citrate.2.Women undergoing controlled ovarian hyperstimulation to induce the development of multiple follicles for Assisted Reproductive Technologies (ART).3.Hypogonadotropic hypogonadism in men. Dosage: Women with anovulatory infertility: Mmenotropin therapy should start within initial 7 days of the menstrual cycle. The initial dose of menotropin is 75-150 IU daily, for at least 7 days. Based on clinical monitoring (including ovarian ultrasound alone/and with measurement of oestradiol levels) subsequent dosing should be adjusted gradually. If a patient fails to respond adequately after 3 weeks of treatment, that cycle should be abandoned and recommence treatment at a higher starting dose. When an optimal response is obtained, a single injection of 5,000 IU to 10,000 IU human chorionic gonadotrophin (hCG) should be given 1 day after the last menotropin injection. This treatment cycle may be repeated at least twice more if necessary. Alternatively, three equal doses of menotropin, each providing 225 to 375 units of FSH with 225 to 375 units of LH, may be given on alternate days followed by hcg one week after the first dose. The patient is recommended to have coitus on the day of and the day following hCG administration. Alternatively intrauterine insemination may be performed. If an excessive response to menotropin is obtained treatment should be stopped and hCG withheld and the patient should use a barrier method of contraception or refrain from having coitus until the next menstrual bleeding has started. Women undergoing controlled ovarian hyperstimulation for multiple follicular development for assisted reproductive technologies (ART):The recommended initial dose of menotropin in women who have received a GnRH agonist for pituitary suppression is 150-225 IU daily for at least the first 5 days of treatment. Based on clinical monitoring (including ovarian ultrasound alone or in combination with measurement of oestradiol levels) subsequent dosing should be adjusted, and should not exceed more than 150 IU per adjustment and do not make dosage adjustments more frequently than every 2 days. The maximum daily dose given should not be higher than 450 IU daily and in most cases dosing beyond 20 days is not recommended. In protocols not involving downregulation with GnRH agonists, menotropin therapy should start on day 2 or 3 of the menstrual cycle. It is recommended to use the dose ranges and regimen of administration suggested above for protocols with downregulation with GnRH agonists. When a suitable number of follicles have reached an appropriate size, a single injection of up to 10,000 IU hCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. Patients should be followed closely for at least 2 weeks after hCG administration. If an excessive response to menotropin is obtained, treatment should be stopped and hCG withheld and the patient should use a barrier method of contraception or refrain from having coitus until the next menstrual bleeding has started. Male infertility: Spermatogenesis is stimulated with chorionic gonadotropin (1000 – 2000 IU two to three times a week) and then menotropin is given in a dose of 75 or 150 units of FSH with 75 or 150 units of LH two or three times weekly. Treatment should be continued for at least 3 or 4 months. **Method of administration:** Administer by intramuscular or subcutaneous injection. **Contraindications:** Menotropin is contraindicated in men and women with: - Tumours of the pituitary or hypothalamic glands, Hypersensitivity to the active substance or any of the excipients used in the formulation.In Men:- Tumours in the testes, Prostate carcinoma. Women with- Ovarian, uterine or mammary carcinoma, Pregnancy and lactation,- Gynaecological haemorrhage of unknown Aetiology, Ovarian cysts or enlarged ovaries not due to polycystic ovarian disease,In the following situations treatment outcome is unlikely to be favourable, and therefore menotropins should not be administered:- Primary ovarian failure, Malformation of sexual organs incompatible with pregnancy,Fibroid tumours of the uterus incompatible with pregnancy, Structural abnormalities in which a satisfactory outcome cannot be expected, for example, tubal occlusion , ovarian, dysgenesis, absent uterus or premature menopause. **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. Last updated on 3/8/2020. For further information, please refer full prescribing information.

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