Abbreviated Prescribing Information of MENOPUR

Indications: ***75IU, 600 IU & 1200 IU:*** Anovulation including polycystic ovarian disease (PCOD) in women unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART). Stimulation of follicular growth in females with hypo- or normogonadotropic ovarian insufficiency.
Dosage & Administration: SC/IM ***Women with anovulation (including PCOD)*** Therapy should start within the initial 7 days of the menstrual cycle. Initially 75-150 IU daily, maintained for at least 7 days. Recommended dose increment: 37.5 IU/adjustment up to 75 IU. Max daily dose: 225 IU. ***Women undergoing controlled ovarian hyperstimulation for multiple follicular development for ART*** Therapy should start approximately 2 weeks after the start of agonist treatment. Initially 150-225 IU daily for at least 1st 5 days of treatment. Dose adjustment should not exceed >150 IU/adjustment. Max daily dose: 450 IU daily. Max duration: 20 days. ***Women with hypo- or normogonadotropic ovarian insufficiency*** Initially 75-150 IU/day. Dose may be increased gradually until there is evidence of estradiol secretion or follicular growth. Maintain dose until pre-ovulation estradiol serum level is achieved. To induce ovulation, administer 5,000-10,000 IU hCG via IM injection 1-2 days after the last dose of HMG.
Contraindications: Hypersensitivity to the active ingredient or any of the excipients; Pituitary or hypothalamic tumours; Ovarian, uterine or mammary carcinoma; Gynaecological haemorrhage of unknown aetiology; Ovarian cysts or enlarged ovaries not due to PCOD; Primary ovarian failure, malformation of sexual organs or fibroid tumours of the uterus incompatible with pregnancy; Pregnancy and lactation.
Warnings and Precautions: Assess fertility and evaluate for hypothyroidism, adrenocortical deficiency, hyperprolactinemia, pituitary or hypothalamic tumours prior to treatment; In cases of ovarian hyperstimulation, withhold hCG and refrain from coitus or use barrier methods for at least 4 days; To follow patients for at least 2 weeks after hCG administration; If severe ovarian hyperstimulation syndrome (OHSS) occurs, gonadotropin treatment should be stopped (especially in patients with PCOD); Potential risk of multiple pregnancy, pregnancy wastage (miscarriage or abortion), ectopic pregnancy, reproductive system neoplasms, congenital malformation and thromboembolic events.
Undesirable Effects: Common (≥1/100 to <1/10): Abdominal pain and distension, nausea, injection site reactions, headache, OHSS, pelvic pain.

Full Prescribing Information available upon request.