

Prior Authorization DRUG Guidelines

**REPRONEX; MENOPUR (Menotropins)**

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

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Repronex (Menotropins) are Gonadotropin Ovulation Stimulators. Menotropins stimulate the development and maturation of the ovarian follicle (FSH), cause ovulation (LH), and stimulate the development of the corpus luteum (LH). Their actions occur as a result of both follicle stimulating hormone (FSH) effects and luteinizing hormone (LH) effects. In men, it stimulates spermatogenesis (LH).

**Pre-Authorization Criteria:**

Menotropin is used in conjunction with hCG to induce ovulation and pregnancy in infertile women experiencing oligoanovulation or anovulation when the cause of anovulation is functional and not caused by primary ovarian failure ( Repronex®). It is also used for stimulation of multiple follicle development in ovulatory patients as part of an assisted reproductive technology (ART) (Menopur®, , Repronex®). Menotropin is used in men for stimulation of spermatogenesis in primary or secondary hypogonadotropic hypogonadism ).

**Repronex®: I.M., SubQ:**

*Induction of ovulation in patients with oligoanovulation (Female):* Initial: 150 int. units daily for the first 5 days of treatment. Adjustments should not be made more frequently than once every 2 days and should not exceed 75-150 int. units per adjustment. Maximum daily dose should not exceed 450 int. units and dosing beyond 12 days is not recommended. If patient's response is appropriate, hCG 5000- 10,000 units should be given one day following the last dose of Repronex®. Hold dose if serum estradiol is >2000 pg/mL, if the ovaries are abnormally enlarged, or if abdominal pain occurs; the patient should also be advised to refrain from intercourse. May repeat process if follicular development is inadequate or if pregnancy does not occur.

*Assisted reproductive technologies (Female):* Initial (in patients who have received GnRH agonist or antagonist pituitary suppression): 225 int. units; adjustments in dose should not be made more frequently than once every 2 days and should not exceed more than 75-150 int. units per adjustment. The maximum daily doses of Repronex® given should not exceed 450 int. units and dosing beyond 12 days is not recommended. Once adequate follicular development is evident, hCG (5000-10,000 units) should be administered to induce final follicular maturation in preparation for oocyte retrieval. Withhold treatment when ovaries are abnormally enlarged on last day of therapy (to reduce chance of developing OHSS).

**Menopur®:** SubQ: *Assisted reproductive technologies (ART):* Initial (in patients who have received GnRH agonist for pituitary suppression): 225 int. units; adjustments in dose should not be made more frequently than once every 2 days and should not exceed more than 150 int. units per adjustment. The maximum daily dose given should not exceed 450 int. units and dosing beyond 20 days is not recommended. Once adequate follicular development is evident, hCG should be administered to induce final follicular maturation in preparation for oocyte retrieval. Withhold treatment when ovaries are abnormally enlarged on last day of therapy (to reduce chance of developing OHSS).

*Spermatogenesis (Male) (unlabeled use):* I.M.: Following pretreatment with hCG: 75 int. units 3 times/week and hCG 2000 units twice weekly until sperm is detected in the ejaculate (4-6 months); may then be increased to menotropins 150 int. units 3 times/week.

VCHCP requires that menotropins and menopur be prescribed by an infertility specialist.

**MONITORING PARAMETERS** — hCG levels, serum estradiol; vaginal ultrasound; in cases of suspected OHSS, monitor fluid intake and output, weight, hematocrit, serum and urinary electrolytes, urine specific gravity, BUN and creatinine, and abdominal girth.

**DOSING: ADULTS** see [Lexi-Comp Online™](#)

**CONTRAINDICATIONS** — Hypersensitivity to menotropins or any component of the formulation; primary ovarian failure as indicated by a high follicle-stimulating hormone (FSH) level; uncontrolled thyroid and adrenal dysfunction; abnormal bleeding of undetermined origin; intracranial lesion (ie, pituitary tumor); ovarian cyst or enlargement not due to polycystic ovary syndrome; infertility due to any cause other than anovulation (except candidates for in vitro fertilization); men with normal urinary gonadotropin

concentrations, elevated gonadotropin levels indicating primary testicular failure; sex hormone-dependent tumors of the reproductive tract and accessory organs; pregnancy.

**WARNINGS / PRECAUTIONS** — For use by infertility specialists. Advise patient of frequency and potential hazards of multiple pregnancy. May cause ovarian hyperstimulation syndrome (OHSS); if severe, treatment should be discontinued and patient should be hospitalized (may become more severe if pregnancy occurs). Monitor for ovarian enlargement; to minimize the hazard of abnormal ovarian enlargement, use the lowest possible dose. Serious pulmonary conditions (atelectasis, acute respiratory distress syndrome) and arterial thromboembolism have been reported. Safety and efficacy have not been established in renal or hepatic impairment, or in pediatric and geriatric patients.

**PREGNANCY RISK FACTOR** — X

**PREGNANCY IMPLICATIONS** — Ectopic pregnancy and congenital abnormalities have been reported. The incidence of congenital abnormality is similar during natural conception.

**LACTATION** — Excretion in breast milk unknown/use caution.

**PATIENT EDUCATION** — Multiple ovulations resulting in plural gestations have been reported.

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