



Prior Authorization Approval Criteria

Antagon (ganirelix)

Generic name:	Ganirelix
Brand name:	Antagon
Medication class:	Infertility drugs
FDA-approved uses:	Inhibits premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH)
Available dosage form:	Ganirelix, disposable, sterile, aqueous solution for SC
Usual dose range:	Multiple dose: 0.25 mg SC once daily during the mid to late portion of the follicular phase after initiating FSH on day 2 or 3 of cycle; continue until hCG is administered
Duration of therapy:	Usually 1 to 6 days.

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Patients undergoing COH for IVF, for whom physician recommended ART
- Infertile women with regular menstrual cycles (25 to 35 days in length)
- Screening follicular phase FSH levels within normal limits
- A transvaginal ultrasound reveals no clinically significant abnormal findings

Criteria for continuation of therapy (*bullet points below are all inclusive unless otherwise noted*):

- Ganirelix should only be used by physicians who are thoroughly familiar with infertility problems.
- Possibility of anaphylactic reaction
- Use caution in women with active allergic conditions or a history of allergies
- Pregnancy must be excluded before starting medication

Monitoring

- • Ultrasound to assess follicle's size
- • WBC, LFTs

Contraindications:

- Known hypersensitivity to ganirelix or any component of the formulation
- Known hypersensitivity to extrinsic peptide hormones, mannitol, gonadotropin releasing hormone (GnRH) or GnRH analogs
- Known or suspected pregnancy; lactation
- Severe renal impairment

Not approved if:

- Prescribed by anyone other than an infertility specialist
- Patients aged 65 or over
- Patients with polycystic ovary syndrome (PCOS)
- Patients with low or no ovarian reserve
- Patients with stage III or IV endometriosis
- More than four cycles

Special considerations:

The pharmacokinetics of this medication have not been studied in the hepatically impaired patients.

FCHP P&T Committee approval: _____ Date: _____ Adopted: 03/15/06