

[Skip to main content](#)

Ganirelix Acetate Injection (Ganirelix)

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The safety of Ganirelix Acetate Injection (ganirelix) was evaluated in two randomized, parallel-group, multicenter controlled clinical studies. Treatment duration for Ganirelix Acetate ranged from 1 to 14 days. Table IV represents adverse events (AEs) from first day of Ganirelix Acetate administration until confirmation of pregnancy by ultrasound at an incidence of $\geq 1\%$ in Ganirelix Acetate-treated subjects without regard to causality.

-TABLE IV: Incidence of common adverse events (Incidence $\geq 1\%$ in Ganirelix Acetate-treated subjects). Completed controlled clinical studies (All subjects-treated group).

Ganirelix Acetate N=794	Adverse Events Occurring in $\geq 1\%$ (n)
4.8 (38)	Abdominal Pain (gynecological)
3.7 (29)	Death Fetal
3.0 (24)	Headache
2.4 (19)	Ovarian Hyperstimulation Syndrome
1.8 (14)	Vaginal Bleeding
1.1 (9)	Injection Site Reaction
1.1 (9)	Nausea
1.0 (8)	Abdominal Pain (gastrointestinal)

During post-marketing surveillance, rare cases of hypersensitivity reactions, including anaphylactoid reactions with the first dose, have been reported (see **PRECAUTIONS**).

Congenital Anomalies

Ongoing clinical follow-up studies of 283 newborns of women administered Ganirelix Acetate Injection (ganirelix) were reviewed. There were three neonates with major congenital anomalies and 18 neonates with minor congenital anomalies. The major congenital anomalies were: hydrocephalus/meningocele, omphalocele, and Beckwith-Wiedemann Syndrome. The minor congenital anomalies were: nevus, skin tags, sacral sinus, hemangioma, torticollis/asymmetric skull, talipes, supernumerary digit finger, hip subluxation, torticollis/high palate, occiput/abnormal hand crease, hernia umbilicalis, hernia inguinalis, hydrocele, undescended testis, and hydronephrosis. The causal relationship between these congenital anomalies and Ganirelix Acetate is unknown. Multiple factors, genetic and others (including, but not limited to ICSI, IVF, gonadotropins, progesterone) may confound ART (Assisted Reproductive Technology) procedures.