GANIRELIX ACETATE Injection

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Ganirelix Acetate Injection	Prefilled Syringe	250 mcg/0.5 mL	1	0548-5001-00

	WHOLESALER ITEM NUMBERS		
NDC#	AMERISOURCE BERGEN	CARDINAL	MCKESSON
0548-5001-00	10267394	5790134	2612091

TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136

AMPHASTAR PHARMACEUTICALS INC.
11570 Sixth Street, Rancho Cucamonga, CA 91730
www.amphastar.com

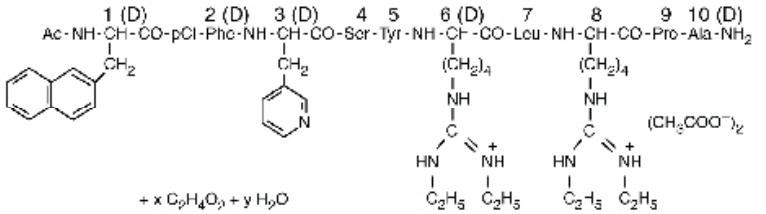
Please see reverse for important safety information, including Warnings and Precautions and Indications and Usage, for Ganirelix Acetate Injection.

Rx Only
06-22
01-509-01

GANIRELIX ACETATE
Injection

DESCRIPTION
Ganirelix Acetate Injection is a synthetic decapeptide with high antagonistic activity against naturally occurring gonadotropin-releasing hormone (GnRH). Ganirelix Acetate is derived from native GnRH with substitutions of amino acids at positions 1, 2, 3, 6, 8, and 10 to form the following molecular formula of the peptide: N-acetyl-3-(2-naphthyl)-D-alanyl-4-chloro-D-phenylalanyl-3-(3-pyridyl)-D-alanyl-L-seryl-L-tyrosyl-N^9,N^{10}-diethyl-D-homoarginyl-L-leucyl-N^9,N^{10}-diethyl-L-homoarginyl-L-prolyl-D-alanylamide acetate. The molecular weight for Ganirelix Acetate is 1570.4 as an anhydrous free base. The structural formula is as follows:

Ganirelix Acetate



Ganirelix Acetate Injection is supplied as a colorless, sterile, ready-to-use, aqueous solution intended for SUBCUTANEOUS administration only. Each single dose, sterile, prefilled syringe contains 250 mcg/0.5 mL of Ganirelix Acetate, 0.1 mg glacial acetic acid, 23.5 mg mannitol, and water for injection adjusted to pH 5.0 with acetic acid, NF and/or sodium hydroxide, NF.

INDICATIONS AND USAGE
Ganirelix Acetate Injection is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

CONTRAINDICATIONS
Ganirelix Acetate Injection is contraindicated under the following conditions:
- Known hypersensitivity to Ganirelix Acetate or to any of its components.
- Known hypersensitivity to GnRH or any other GnRH analog.
- Known or suspected pregnancy (see PRECAUTIONS).

WARNINGS
Ganirelix Acetate Injection should be prescribed by physicians who are experienced in infertility treatment. Before starting treatment with Ganirelix Acetate, pregnancy must be excluded. Safe use of Ganirelix Acetate during pregnancy has not been established (see CONTRAINDICATIONS and PRECAUTIONS).

PRECAUTIONS
General
Special care should be taken in women with signs and symptoms of active allergic conditions. Cases of hypersensitivity reactions, including anaphylactoid reactions, have been reported, as early as with the first dose, during post-marketing surveillance (see ADVERSE REACTIONS). In the absence of clinical experience, Ganirelix Acetate treatment is not advised in women with severe allergic conditions.

ADVERSE REACTIONS
The safety of Ganirelix Acetate Injection 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 ≥ 1% in Ganirelix Acetate-treated subjects without regard to causality.

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

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

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

Congenital Anomalies
Ongoing clinical follow-up studies of 283 newborns of women administered Ganirelix Acetate Injection 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.

OVERDOSAGE
There have been no reports of overdosage with Ganirelix Acetate Injection in humans.