FERTAGYL® (gonadorelin)

- FERTAGYL is a sterile solution containing 43 μg/mL gonadorelin (GnRH; equivalent to 50 μg/mL gonadorelin diacetate tetrahydrate)
- FERTAGYL is indicated for the treatment of ovarian follicular cysts in dairy cattle
- FERTAGYL initiates release of endogenous LH to cause ovulation and luteinization
- Recommended intramuscular or intravenous dosage is 2 mL
- Keep refrigerated at 36° - 46°F (2° - 8°C)
ANADA 200-134, Approved by FDA
FERTAGYL® (gonadorelin)
For Animal Use Only
FOR INJECTION FOR THE TREATMENT OF CYSTIC OVARIANCES IN CATTLE

Description
FERTAGYL® is a sterile solution containing 43 μg/mL gonadorelin (GnRH; equivalent to 50 μg/mL gonadorelin diacetate tetrahydrate) suitable for intramuscular or intravenous administration. Gonadorelin is a decapptide composed of the sequence of amino acids – 5-oxoPro-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH₂ with a molecular weight of 1182.32 and empirical formula C₅₅H₇₅N₁₇O₁₃. Gonadorelin is the hypothalamic releasing factor responsible for the release of gonadotropins (e.g., LH, FSH) from the anterior pituitary. Synthetic gonadorelin is physiologically and chemically identical to the endogenous bovine hypothalamic releasing factor.

Pharmacology and Toxicology
Endogenous gonadorelin is synthesized by and/or released from the hypothalamus during various stages of the bovine estrous cycle following appropriate neurogenic stimuli. It passes via the hypophyseal portal vessels, to the anterior pituitary to effect the release of gonadotropins.

Synthetic gonadorelin administered intramuscularly or intravenously also causes the release of endogenous LH and FSH from the anterior pituitary. Gonadorelin diacetate tetrahydrate has been shown to be safe. The LD₅₀ for mice and rats is greater than 60 mg/kg, and for dogs, greater than 600 μg/kg, respectively.

No untoward effects were noted among rats or dogs administered 120 μg/kg/day intramuscularly or 72 μg/kg/day intravenously for 15 days.

It had no adverse effects on heart rate, blood pressure or EKG, when administered to unanesthetized dogs at 60 μg/kg. In anesthetized dogs it did not produce depression of myocardial or systemic hemodynamics or adversely affect coronary oxygen supply or myocardial oxygen requirements.

The intravenous administration of 60 μg/kg/day gonadorelin diacetate tetrahydrate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects.

The intramuscular administration of 1000 μg gonadorelin diacetate tetrahydrate to normally cycling dairy cattle had no effect on hematology or blood chemistry. Further, gonadorelin diacetate tetrahydrate did not cause irritation at the site of intramuscular administration in dogs. The dosage administered was 72 μg/kg/day for 7 days.

Indication and Dosage
FERTAGYL® (gonadorelin) is indicated for the treatment of ovarian follicular cysts in dairy cattle. Ovarian cysts are non-ovulated follicles with incomplete luteinization which result in nymphomania or irregular estrus. Historically, cystic ovaries have responded to an exogenous source of luteinizing hormone (LH) such as human chorionic gonadotropin. FERTAGYL® initiates release of endogenous LH to cause ovulation and luteinization. The recommended intramuscular or intravenous dosage of FERTAGYL® is 86 μg/cow (2 mL; equivalent to 100 μg gonadorelin diacetate tetrahydrate/cow).

Each mL of FERTAGYL® contains: Gonadorelin 43 μg, Benzyl Alcohol 9 mg, Sodium Chloride 7.47 mg, Water for Injection, PhEur. q.s., pH adjusted with sodium phosphate (monobasic and dibasic).

Keep refrigerated: 2° - 8°C (36° - 46°F).

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

How Supplied: FERTAGYL® is available in a concentration of 43 μg/mL (equivalent to 50 μg/mL gonadorelin diacetate tetrahydrate) suitable for intramuscular or intravenous administration. FERTAGYL® is supplied in multidose vials containing 20 mL of sterile solution.

Manufactured for: INTERVET INC. (d/b/a Merck Animal Health) Summit, NJ 07901
By: INTERVET INTERNATIONAL GmbH, Unterschleissheim – Germany