fertagyl®
(gonadorelin)

Get the job done with the #1 GnRH on the market.[1]

FERTAGYL® (gonadorelin) improves reproductive efficiency by synchronizing estrous cycles and treating cystic ovaries.

FERTAGYL makes fertility simple and is approved for:

- The treatment of cystic ovaries in dairy cattle.
- Use with ESTRUMATE® (cloprostenol injection) to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.
- Use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in beef cows.

Increased efficiency and peace of mind.

Research has shown that FERTAGYL produces high ovulation and pregnancy rates.[2,3] To increase your herd's reproductive efficiency, choose a synchronization program that includes both FERTAGYL and ESTRUMATE.

An option that fits your operation.

There are many options for synchronization of estrus and ovulation in cattle. Your veterinarian can help you determine which one is right for you.

For more information, talk to your veterinarian or visit MAHCattle.com.

DOSAGE & ADMINISTRATION

- Each mL of FERTAGYL contains 43 mcg of gonadorelin.
- **For treatment of cystic ovaries:** administer 2 mL per cow via intravenous or intramuscular injection.
- **For estrous synchronization:** administer 2 mL per cow via intravenous or intramuscular injection in accordance with the FTAI protocol as described in the package insert.
- **For complete directions and dosing regimen,** refer to the package insert.

PRESENTATIONS

- Available in 100 mL and 20 mL bottles.

[1]Animalytix, MAT. May 2020.
[2]Luchterhand M, et al. Ovulation and fertility response to commercially available GnRH products in lactating cows synchronized with the Double-Ovsynch protocol. *Anim Reprod Sci*. 2019;202:42-48.
[3]Souza AH, et al. Comparison of gonadorelin products in lactating dairy cows. *Theriogenology*. 2009;72:271-279.

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MERCK
Animal Health

FERTAGYL®

(gonadorelin)

43 mcg/mL gonadorelin Injectable Solution

For treatment of cystic ovaries in dairy cattle
For use with Estrumate (cloprostenol injection) to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows
For use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in beef cows

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

DESCRIPTION:
Fertagyl is a sterile solution containing 43 mcg/mL of gonadorelin (GnRH: as gonadorelin acetate) suitable for intramuscular or intravenous administration according to the indication. Gonadorelin is a decapeptide composed of the sequence of amino acids -

5-oxoPro-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH_2

a molecular weight of 1182.32 and empirical formula $C_{55}H_{75}N_{17}O_{13}$.

Each mL of Fertagyl contains:

Gonadorelin (as gonadorelin acetate)	43 mcg
Benzyl Alcohol	9 mg
Sodium Chloride	7.47 mg
Water for Injection, USP	q.s.

pH adjusted with sodium phosphate (monobasic and dibasic).

Gonadorelin is the hypothalamic releasing factor responsible for the release of gonadotropins (e.g., luteinizing hormone [LH], follicle stimulating hormone [FSH]) from the anterior pituitary.

Synthetic gonadorelin is physiologically and chemically identical to the endogenous bovine hypothalamic releasing factor.

INDICATIONS FOR USE:
Cystic Ovaries
Fertagyl 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 LH such as human chorionic gonadotropin.
Fertagyl initiates release of endogenous LH to cause ovulation and luteinization.

Reproductive Synchrony
Fertagyl is indicated for use with Estrumate (cloprostenol injection) to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.
Fertagyl is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in beef cows.

DOSAGE AND ADMINISTRATION:
Cystic Ovaries
The intravenous or intramuscular dosage of Fertagyl is 86 mcg gonadorelin (2 mL) per cow.

Reproductive Synchrony
For lactating dairy cows, the intramuscular dosage of Fertagyl is 86 mcg gonadorelin (2 mL) per cow, used in reproductive synchrony programs similar to the following:
- Administer the first Fertagyl injection (2 mL) on Day 0.
- Administer 2 mL of Estrumate (500 mcg cloprostenol, as cloprostenol sodium) by intramuscular injection 6 to 8 days after the first Fertagyl injection.
- Administer the second Fertagyl injection (2 mL) 30 to 72 hours after the Estrumate injection.
- Perform FTAI 8 to 24 hours after the second Fertagyl injection, or inseminate cows on detected estrus using standard herd practices.

For beef cows, the intramuscular dosage of Fertagyl is 86 mcg gonadorelin (2 mL) per cow, used in reproductive synchrony programs similar to the following:
- Administer the first Fertagyl injection (2 mL) on Day 0.
- Administer 500 mcg cloprostenol (as cloprostenol sodium) by intramuscular injection 6 to 8 days after the first Fertagyl injection.
- Administer the second Fertagyl injection (2 mL) 30 to 72 hours after the cloprostenol sodium injection.
- Perform FTAI 0 to 24 hours after the second Fertagyl injection, or inseminate cows on detected estrus using standard herd practices.

WARNINGS AND PRECAUTIONS:
Not for use in humans. Keep out of reach of children.

WITHDRAWAL PERIODS:
No withdrawal period or milk discard time is required when used according to the labeling.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Intervet at 1-800-211-3573. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/reportanimalae.

PHARMACOLOGY AND TOXICOLOGY:
Endogenous gonadorelin is synthesized 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 (e.g. LH, FSH). Synthetic gonadorelin administered intravenously or intramuscularly also causes the release of endogenous LH or FSH from the anterior pituitary.
Gonadorelin acetate has been shown to be safe. The LD_{50} for mice and rats is greater than 60 mg/kg, and for dogs, greater than 600 mcg/kg, respectively. No adverse effects were noted among rats or dogs administered 120 mcg/kg/day or 72 mcg/kg/day intravenously for 15 days.
It had no adverse effects on heart rate, blood pressure, or EKG to unanesthetized dogs at 60 mcg/kg. In anesthetized dogs it did not produce depression of myocardial or system hemodynamics or adversely affect coronary oxygen supply or myocardial oxygen requirements.
The intravenous administration of 60 mcg/kg/day gonadorelin acetate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects.
Further, gonadorelin acetate did not cause irritation at the site of intramuscular administration in dogs with a dose of 72 mcg/kg/day administered for seven (7) days.

TARGET ANIMAL SAFETY:
In addition to the animal safety information presented in the PHARMACOLOGY AND TOXICOLOGY section, the safety of gonadorelin was established through the review and evaluation of the extensive published literature available for the use of gonadorelin-containing products.
The intramuscular administration of 860 mcg gonadorelin (as gonadorelin acetate) on five (5) consecutive days to normally cycling dairy cattle had no effect on hematology or clinical chemistries.
In field studies evaluating the effectiveness of gonadorelin for the treatment of ovarian follicular cysts, the incidence of health abnormalities was not significantly greater in cows administered gonadorelin than cows administered a placebo injection.
The target animal safety of, and injection site reactions to, Fertagyl when used with Estrumate (cloprostenol injection) were evaluated during the conduct of effectiveness field studies in lactating dairy cows. The incidence of health abnormalities was not significantly greater in cows administered Fertagyl than cows administered a placebo injection.
The target animal safety of, and injection site reactions to, gonadorelin when used with cloprostenol sodium were evaluated during the conduct of effectiveness field studies in beef cows. The incidence of health abnormalities was not significantly greater in cows administered gonadorelin than cows administered a placebo injection.

IMPORTANT SAFETY INFORMATION FOR FERTAGYL: Not for use in humans. Keep out of reach of children.

IMPORTANT SAFETY INFORMATION FOR ESTRUMATE: Women of childbearing age, asthmatics, and persons with respiratory problems should exercise extreme caution when handling ESTRUMATE. ESTRUMATE is readily absorbed through the skin and may cause abortion and/or bronchospasms; direct contact with the skin should be avoided and accidental spillage on the skin should be washed off immediately with soap and water. Do not administer ESTRUMATE to a pregnant cow if abortion is not desired. Severe localized post-injection clostridial infections have been reported; in rare instances infection has led to death. At 50 and 100 times the recommended dose, mild side effects may be detected. For complete information on ESTRUMATE, see package insert.

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