

TIMELY, EFFICIENT REPRODUCTION TO ADVANCE YOUR HERD





BOVILIS® Vista® 5 VL5 SQ CFP

THE SIGNIFICANCE OF BEEF CATTLE REPRODUCTION

Reproduction is the No. 1 economically important trait in beef cattle - 10 times more important than growth traits and 20 times more important than carcass traits.

For every 21 days cows are open, between 20 and 40 pounds of weaning weight is lost.^{1,2}



Benefits of calving in the first 21 days

Records collected for more than a decade at the University of Nebraska-Lincoln (UN-L) showed that steer calves born in the first 21 days had greater weaning body weights, carcass weights, marbling scores and yield grades. Replacement heifers born during the first 21 days were heavier at weaning, pre-breeding and pre-calving. A greater percentage of those heifers cycled before breeding and had higher pregnancy rates.³

Another study demonstrated heifer calves born within the first 21 days of the calving season perform better at maturity. Earlier-born heifers weaned heavier calves and had greater longevity in the herd as mature cows, compared to heifers born later in the calving season.¹

For every 21 days cows are open, between **20** and **40** pounds of weaning weight is lost.^{1,2}

A simple solution: heat synchronization

Heat synchronization can help manage the timing of your breeding and calving seasons, whether you bull breed or use artificial insemination (AI). Getting more cows pregnant in the first 21 days delivers these benefits:



Earlier conception

 $\overline{\wedge}$ Increased weaning weights

í\$ Increased profit potential

FS More uniform calf crop

Get cows bull bred faster

Another UN-L study evaluated how heat synchronization affects calving distribution - and how time of calving affects carcass characteristics.² The study compared calves from unsynchronized, 60day breeding seasons with calves from synchronized, 45-day breeding seasons. Heat was synchronized with a single injection of prostaglandin 4.5 days (108 hours) after turning mixed-age bulls in with the cow herd. Study results show these benefits of synchronization:

- More cows calved during the first 21 days
- Calves were 20 pounds heavier at weaning
- Calves born in the first 21 days had greater carcass weights and marbling scores and better yield grades
- Shortened breeding season from 60 to 45 days
- Heavier, more valuable carcasses, which were worth an additional \$77 per carcass at the feedlot

With delayed calving time, the percentage of steers grading premium choice or better decreased, as did the total carcass value.

Consult your veterinarian for recommendations on a heat synchronization management protocol that works for your operation. The Beef Reproduction Task Force at BeefRepro.org also offers protocols and resources.

The importance of reproductive vaccine prevention

In addition to getting cows bred in the first 21 days, it's important to protect them from reproductive diseases through the critical breeding and gestation periods. Vaccinations for cows and first-calf heifers should focus on optimizing conception and preventing reproductive loss.



Estrumate[®] (cloprostenol injection)

Prostaglandin

ESTRUMATE (cloprostenol injection) is a leading prostaglandin that allows producers to manage heat detection, breeding and calving intervals, whether using bull breeding or AI. This reproductive tool is a strong luteolytic agent.

ESTRUMATE is approved for use in beef cows and replacement beef heifers for:

- Unobserved or non-detected estrus
- Treatment of pyometra or chronic endometritis
- Treatment of mummified fetus
- Treatment of luteal cysts
- Estrus synchronization
- Termination of unwanted pregnancies

IMPORTANT SAFETY INFORMATION: 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.



Estrumate[®] (cloprostenol injection) 250 mcg cloprostenol/ml elent to 263 mcg

is drug to use by or on

MERCK



visit **Estrumate.com** or scan the QR code using the camera on your phone.



FERTAGYL (gonadorelin) is approved for use with cloprostenol sodium to synchronize heat cycles to allow for the convenience of fixed-time AI (FTAI) in beef cows. By managing breeding timing through FTAI, producers can achieve more pregnancies in the first 21 days of the breeding season.

Beef veterinarians and producers can use FERTAGYL and ESTRUMATE in their breeding programs with the goal of simplifying fertility and supporting reproductive efficiency and performance.

The effectiveness of FERTAGYL for use with ESTRUMATE was demonstrated in a field study at 10 different U.S. locations.⁶ Pregnancy rate to FTAI was significantly greater in cows treated with FERTAGYL than in cows treated with a placebo.

The type of gonadorelin makes a big difference, and FERTAGYL is formulated for results. FERTAGYL contains gonadotropin acetate, proven to be more effective than gonadorelin hydrochloride. In a study of more than 1,400 dairy cows, ovulation response was 11.2 percentage units higher and pregnancy per Al was 6.8 percentage units higher for gonadorelin acetates.⁷

IMPORTANT SAFETY INFORMATION: Not for use in humans. Keep out of reach of children. For complete information on FERTAGYL, see package insert.

WHY FERTAGYL?



#1 GnRH on the market⁴



GONADORELIN ACETATE for better results^{7,8}



HIGH OVULATION AND PREGNANCY RATES^{7,9}



SIMPLIFIES success with FTAI



TRUSTED for nearly 25 years

For more information, visit Fertagyl.com

or scan the QR code using the camera on your phone.





BOVILIS® Vista[®] 5 VL5 SQ CFP

Reproductive Vaccine

A reproductive management program for beef herds is not complete without comprehensive fetal protection. When vaccinating pre-breeding, BOVILIS VISTA 5 VL5 SQ CFP vaccine protection begins in the critical first trimester. Protection continues throughout the entire pregnancy with demonstrated reproductive protection that is unequaled.

BOVILIS VISTA 5 VL5 SQ CFP has been shown effective against respiratory disease and abortion due to IBR, respiratory disease and fetal infection, including persistently infected (PI) calves due to BVD Types 1 and 2, BRSV and Pl₃, and five strains of leptospirosis, including Lepto hardjo-bovis (LHB) and Campylobacter fetus (Vibrio).

It is the **only** modified-live reproduction vaccine to offer:

- Proven effectiveness against fetal infection, including PI calves caused by BVD Types 1 and 2
- An administration window that allows dosing as close as two weeks prior to breeding

It has demonstrated efficacy and duration of immunity against disease caused by the most prevalent BVD subtype - Type 1b.10

WHY BOVILIS VISTA 5 VL5 SQ CFP?

COMPLETE BVD PROTECTION for the entire pregnancy¹¹

MERCK

MADE IN THE USA

PROTECTION from 11 viruses and bacteria

SAFE for use in pregnant cows/heifers and nursing calves^{*}

MODIFIED-LIVE VACCINE provides long-lasting immunity

PROVEN to cause fewer reactions¹²

*Provided they were previously vaccinated with a modified-live virus BOVILIS VISTA vaccine. See package insert for more information.

For more information. visit ChooseBOVILIS.com

or scan the QR code using the camera on your phone.



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Estrumate[®] (cloprostenol injection)

250 mcg cloprostenol/mL (equivalent to 263 mcg cloprostenol sodium/mL) A sterile solution of a prostaglandin F2α analogue for intramuscular injection in beef cows, lactating dairy cows, and replacement eef and dairy heifer Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Caution: rederal (USA) and resorts unis drug to use by or on or other the analysis. **DESCRIPTION** Estrumate® (cloprostano) injection) is a synthetic prostaglandin analogue structurally related to prostaglandin F2 or (PGF2 or). Each mL of the sterile colorless aqueous solution contains 250 mgc cloprostenol (equivalent to ZB3 mgc cloprostenol sodium). Is mg sodium citrate, US5 mg anhydrous citric acid, 6.7 mg sodium chloride, 20 mg benzyl alcohol, and water for injection, q.s.



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. For treatment of pyometra or chronic endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers

2. For treatment of pyometra or chronic endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers
3. For treatment of mummited featus in beef cows, lactating dairy cows, and replacement beef and dairy heifers
4. For treatment of luteal cysts in beef cows, lactating dairy cows, and replacement beef and dairy heifers
5. For abortion of beef cows, lactating dairy cows, and replacement beef and dairy heifers
6. For estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers
6. For estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers
7. For use with Feragy¹⁰ (gonadorelin to synchronize estrus cycles to allwork for ked time artificial insemination (FTAI) in lactating dairy cows.
Strutter causes functional and morphological regression of the corpus luteum (luteolysis) in cattle. In normal, non-pregnant cycling animals, this effect on the life span of the corpus luteum cually results in estrus 2 to days after treatment. In animals with prolongel duite al function (gyometra, mummitied fetus, and luteal cysts), the induced luteolysis usally results in resolution of the condition and return to cyclicity.

regnant animals may abort depending on the stage of gestation.

Descate AnD DAMINISTRATION: Two mL of Estrumate (500 mcg cloprosteno) should be administered by INTRAMUSCULAR INJECTION using the specific dosage regimen for the indication. Zom L, bottle size: Use within 28 days of first puncture. 100 mL bottle size: Use within 28 days of first puncture and puncture a maximum of 12 times. Use only with automatic injection equipment or repeater syringe. Discard bottle after one stopper puncture with draw-off

- 1 . For unobserved or non-detected estrus in beef cows, lactating dairy cows, and replacement beef and dairy heifers

- 1. For unobserved or non-detected estrus in beef cows, lactating dairy cows, and replacement beef and dairy befires Cows and heires which are not detected in estrus, although ovarian cyclicity continues, can be treated with Estrumater if a mature corpus lateum is present. Estrus is expected to occur 2 to 5 days following injection, at which time animals may be inseminated. Treated animals may should be inseminated at the usual time following detection of estrus. If estrous detection is not desirable or possible, treated animals may be inseminated thread usual time following detection of estrus. If estrous detection is not desirable or possible, treated animals may be inseminated thread to romice endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers Damage to the reproductive tract at calving or postpartum retention of the placenta often leads to infection and inflammation of the uterus (endometrix). Under certain circumstances, this may progress into chronic endometrix with the uterus becoming distended with purulent matter. This condition, commonly referred to as pyometra, is characterized by a lack of cyclical estrous behavior and the presence of a persistent corpus lateur. Induction of luteolysis with Estrumate usually results in evacuation of the uterus and a return to normal cyclical activity within 14 days after treatment. After 14 days post-treatment, recovery rate of treated animals will not be different than that of untreated cathe.
- 3. For treatment of mummified fetus in beef cows, lactating dairy cows, and replacement beef and dairy heifers
- accompanied by no external signs and by no changes in palpable consistency of the uterus). Treatment with Estrumate can restore norma on of the luteal cyst.
- ovarian activity by causing regression of the luteal cyst. 5. For abortion of beef cows, lactating dairy cows, and replacement beef and dairy heiters
- 5. For abortion of beet cows, lactaing dairy cows, and replacement beet and dairy heiters Unwanted pregnancies can be safely and efficiently terminated from 1 week after mating until about 5 months of gestation. The induced abortion is normally uncomplicated and the fetus and placenta are usually expelled about 4 to 5 days after the injection with the reproductive tract returning to normal soon after the abortion. The ability of Estimate to induce abortion decreases beyond the fifth month of gestation while the risk of dystocia and its consequences increases. Estrumate has not been sufficiently tested under feedlot conditions; therefore, recommendations cannot be med for its use in hefers placed in feedlots.
 6. For estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers allows control of the time at which cycling cows or heifers can be bred. Estrumate can be used in a breeding program with the following methods:

- methods: Single Estrumate injection: Only animals with a mature *corpus luteum* should be treated to obtain maximum response to the single injection. However, not all cycling cattle should be treated since a mature *corpus luteum* is present for only 11 to 12 days of the 21 day cycle. Prior to treatment, cattle should be examined rectally and found to be anatomically normal, be non-pregnant, and have a mature *corpus luteum*. If these criteria are met, estrus is expected to occur 2 to 5 days following injection, at which time animals may be inseminated. Treated cattle should be inseminated at the usual time following detection of estrus. If estrous detection is not destrable or possible, treated animals may be inseminated at ther usua time following attributive at about 22 and 58 hours post-injection. With a sin possible, realed animals may be inseminated either once at about 27 hours of whice at about 72 and so hours possible usaws with injection program, it may be desirable to assess the cyclicity status of the hord before Estrumate treatment. This can be accomp by heat detecting and breeding at the usual time following detection of estrus for a 6-day period, all prior to injection. If by the a the cyclicity status appears normal (approximately 25%-33% detected in estrus), all cattle not already inseminated should be pa tion of estrus for a 6-day period, all prior to injection. If by the sixth da the cynchicly status appears you man application with the status of the cynchic status and the status appears and the status appears and the plaquet for normality, non-pregnancy, and explicitly, and the status of the status and the status and the status and the signs of the status appears and the status appears and the status appears and the status and the status appears status appears and the status appears a
- signs of estrus on the seventh and eighth days. On the ninth and tenth days, breeding may continue at the usual time following detection of estrus, or all cattle not already inseminated may be herd either once on the ninth day (at about 72 hours post-injection) on both the ninth and tenth days (at about 72 and 96 hours post-injection). Double Estrumate injections, prior to treatment, cattle should be examined rectally and found to be anatomically normal, non-pregnant, and cycling (the presence of a mature *capus luteum*) is not necessary when the first injection of a double injection regimen is given). A second injection should be given 11 days after the first injection. In normal, cycling (the presence of a mature *capus luteum*) is not necessary when the first injection of a double injection regimen is given). A second injection. Treated cattle should be inseminated at the usual time following detection of estrus. If estrosus detection is not desirable or possible, treated animals may be inseminated at the usual time following detection of estrus. If estrosus detection is not desirable rollowing detected estrus. Annimals not inseminated shoul receive a second injection 11 days after the first injection. Animals returning to estrus after the seminated at the usual time following detection of estrus or may be inseminated at the usual time following detection of estrus or may be inseminated at the usual time following detection and inseminating or hand mating any animals returning to estrus, or observing animals (especially during the third week fater injection and inseminating or hand mating any animals returning to estrus, or turning in clean-up bulk)[5 to 7 days after the last injection of Estrumate to cover any animals returning to estrus. Management considerations for use of Estrumate for estrus synchronization: A variety of programs can be designed to best meet the needs of individual management systems. A breeding program should be eslected which is aspropriate for the usisting circumstanc
- A variety of programs can be designed to best meet the needs of individual management systems. A breeding program should be select which is appropriate for the existing circumstances and management practices. Before a breeding program is planned, the producer's objectives must be examined and the producer must be made aware of the projected results and limitations. The producer and the consulting veterinarian should review the operation's breeding history, herd health, and nutritional status and agree that a breeding program is practical in the producer's specific situation. For any successful breeding program: cows and heires must be normal, non-pregnant, and cycling (rectat Japation should be performed); cows and heires must be in sound breeding condition and on an adequate or increasing plane of nutrition; specer comergen blanking and the cond blanking are a constrictive.
- cows and heiters must be in sound breading condition and on an adequate or increasing plane of nutrition; proper program planning and record keeping are essential;
 if artificial insemination is used, it must be performed by competent inseminators using high-quality semen.
 tis important to understand that Estrumate is effective only in animals with a mature *corpus* luterum (ovulation must have occurred at least This important to uncersation that causal and the sense of the sense o
- following a single Estrumate injection. 7. For use with Fertagyl® (gonadorelin) to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy

cows Use in reproductive synchrony programs similar to the following: • Administer the first Fertagyl[®] injection (2 mL; 86 mcg gonadorelin, as gonadorelin acetate) by intramuscular injection on Day 0. • Administer 2 mL of Estrumate by intramuscular injection 6 to 8 days after the first Fertagyl[®] injection. • Administer the second Fertagyl[®] injection (2 mL; 86 mcg gonadorelin, as gonadorelin acetate) 30 to 72 hours after the Estrumate injection. • Administer the second Fertagyl[®] injection (2 mL; 86 mcg gonadorelin, as gonadorelin acetate) 30 to 72 hours after the Estrumate injection.

CONTRAINDICATIONS: Do not use this drug product in pregnant cattle, unless abortion is desired. ARNINGS AND PRECAUTIONS

WITHDRAWAL PERIODS AND RESIDUE WARNINGS

No milk discard or pre-slaughter drug withdrawal period is required when used according to labeling. Use of this product in excess of the approved dose may result in drug residues.

USER SAFETY WARNINGS:

- USER SAFETY WARNINGS: Not for use in humans. Keep this and all drugs out of the reach of children. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Estrumate is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water. To obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Merck Animal Health at 1-800-211-3573 or http://www.merck.com ANIMAL SAFETY WARNINGS:
- ANIMAL SAFETY WARININGS: As with all parentireal products, careful aseptic techniques should be employed to decrease the possibility of post-injection bacterial infection. Severe localized clostridial infections associated with injection of Estrumate have been reported. In rare instances, such infections have resulted in death. Aggressive antibilitoit brerzy should be employed at the first sign of infection at the injection site, whether localized or diffuse. At 50 and 100 times the recommended dose, mild side effects may be detected in some cattle. These include increased uneasiness, slight frothing, and milk let-down

- In doming und minuted sorted. CONTACT INFORMATION: To report suspected adverse drug experiences, call Merck Animal Health at 1-800-211-3573. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at http://www.tda.gov/reportanimalae
- HOW SUPPLIED: 20 mL and 100 mL multidose vials
- STORAGE, HANDLING, AND DISPOSAL
- 2. Store in carton. 3. Store at 2-30°C (36-86°F).
- See FDA's website http://www.tda.gov/safesharpsdisposal for information on safe disposal of needles and other sharps. Approved by FDA under NADA # 113-645
- Copyright © 2017 Intervet Inc (d/b/a Merck Animal Health) a subsidiary of Merck & Co., Inc. Madison, NJ 07940 All rights reserved. Made in Germany Rev. 12/2018

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FERTAGYL	®	(gonadorelin)
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43 mcg/mL gonadorelin Injectable Solutio For treatment of cystic ovaries in dairy cattle

For use with Estrumate (coprosetion) integrity account of the section of the sect

For use with clopros

CAUTION:

leral law restricts this drug to use by or on the order of a licensed veterinarian

DESCRIPTION:

 DESCRIPTION:

 Fertagy is a starile solution containing 43 mcg/mL of gonadorelin (GnRH: as gonadorelin acetate) suitable for intramuscular or intravenous administration according to the indication. Conadorelin is a decapeptide composed of the sequence of amino acids – 5-oxoPro-His-Trp-Ser-Tyr-Giy-Lte-Arg-Pro-Giy-NH, a molecular weight of 1182:32 and empirical formula C_mH_mN_mO₁₀.

 Gonadorelin (as gonadorelin acetate)
 643 mcg

 Benzyl Alcohol
 9 mg

 Sodium Chloride
 7.47 mg

 Water for Injection, USP
 q.8

 PH adjusted with sodium phosphate (monobasic and dibasic).
 q.8
 pr adjuster vini sounim prospirate (monobasic and unasic). Gonadorelinis the hypothalamic releasing factor responsible for the release of gonadortopins (e.g., luteinizing hormone [LH], follicle stimulating hormone [FSH]) from the anterior pituitary. Synthetic gonadrolini is physiologically and chemically identical to the endogenous bovine hypothalamic releasing factor. INDICATIONS FOR LISE

ysuc ovaries ertaoy is indicated for the treatment of ovarian follicular cysts in dairy cattle. Ovarian cysts are non-ovulated follicles with incomplete

le rady in sinuctato un lie a estanen or vonarar nalicara i ysa a rady caute. Vonan vysa are nor vouseeu um Iluterinization which result in nymphomania or rady are strus. Historically, cystic ovaries have responded to an exogenous source of LH such as human chorionic gonadotropin. Fertagy linitates release of endogenous LH to cause ovulation and luterinization.

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

DOSAGE AND ADMINISTRATION:

Reproductive Synchromy For lactating dairy cows, the intramuscular dosage of Fertagyl is 86 mcg gonadorelin (2 mL) per cow, used in reproductive synchrony program: similar to the following: - Administer the fore Exercised International Inte 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

iniection.

injection. • Administer the second Fertagyl injection (2 mL) 30 to 72 hours after the Estrumate injection. • Perform FTAI & 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:

 Hor DeeP Cows, the Internative usage of its approximate a state of the following:

 • Administer the first Fertagyl injection (2 mL) on Day 0.

 • Administer Do more 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.new.owen.com, and the set of the safety Data Sheet (SDS), contact Intervet at 1-888-FDA-VETS, or http://www.new.owen.com, contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS", contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS", contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS", contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS", contact FDA at 1-888-FDA-VETS, contact FDA at 1-888-FDA-VETS, contact FDA-VETS, contact FDA-VETS", contact FDA-VETS, contact FDA-VETS, contact FDA-VETS, cont

ARMACOLOGY AND TOXICOLOGY

approve gonadorini is synthesized and/or released from the hypothalamus during various stages of the bovine estrous cycle following opriate neurogenic stimuli. It passes via the hypophyseal portal vessels, to the anterior pituitary to effect the release of gonadotropins [e.

ric conadorelin administered intravenously or intramuscularly also causes the release of endogenous LH or FSH from the anterior Gonadorelin acetate has been shown to be safe. The LD₅₀ for mice and rats is greater than 60 mg/kg, and for dogs, greater than 600 mcg/kg,

uousaoreim acetate nas been shown to be safe. The LD_a for mice and ratis is greater than B0 mg/kg, and for dogs, greater than B0 mg/kg. respectively, No adverse effects were noted among ratis or dogs administered 20 mg/kg/ay or travenously for 15 days. It had no adverse effects on heart rate, blood pressure, or EKG to unanesthetized dogs at 60 mg/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 mg/kg/day gonadorelin acetate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or tratatogenic effects. Further, gonadorelin acetate did not cause eritration at the site of intramuscular administration in dogs with a dose of 72 mg/kg/day administered for seven (7) days.

TARGET ANIMAL SAFETY:

TARGET ANIMAL SAFET: 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 800 mcg gonadorelin (as gonadorelin acetate) on five (5) consecutive days to normally cycling dairy cattle had no effect on hematology or clinical chemistrise. 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 to the treatment of ovarian follicular cysts, the incidence of health abnormalities was not significantly greater in cows administered gonadorelin to the treatment of ovarian follicular cysts, the incidence of health abnormalities was not significantly greater in cows administered gonadorelin to the treatment of ovarian follicular cysts, the incidence of health abnormalities the target animal safety of, and injection site reactions to, Fertagly when used with Estrumate (6)oprostenol 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 a placeto injection. The target animal safety of, and injection site reactions to, gonadorelin when used with clorostenol sodium were evaluated during the conduct of effectiveness field studies in bect cons. The incidence of health abnormalities was not significantly greater in cows administered gonadorelin than cows administered a placeto injection. **Effectiveness** field studies in bect cons. The incidence of health abnormalities was not significantly greater in cows administered gonadorelin than cows administered aplaceto injection.

EFFECTIVENESS:

EFFECTIVENESS: The use of gonadorelin for treatment of ovarian follicular cysts in dairy cattle was demonstrated to be effective with a treatment dose of 86 mog gonadorelin (as gonadorelin acetate). The effectiveness of Fertagy (for use with Estimate (cloprosteno) injection) to synchronize estrous cycles to allow for FTAI in lactating dairy cows was demonstrated in a field study at six different locations in the U.S. A total of 780 healthy, non-pregnant primiparous or multiparous lactating dairy cows within 50-120 days postpartum were enrolled in the study. A total of 371 cows were administered Fertagy(12 mL; 86 mog gonadorelin as the acetate sait) and 381 cows were administered an equivalent volume of saline as an intramuscular injection twice in the following regimen: Day 0: 2 mL Fertagyl or saline

Day 0: 2m. Fertagy (or saline Day 7: 2m. Estrumate (cloprostenol injection) Day 9: 2m. Estrumate (cloprostenol injection) Exed time Al was performed on Day 10, 16 ± 8 hours after the Day 9 injection. Cows were evaluated for pregnancy on Day 45 ± 5 days by trans-rectai lutrasound or rectal palpation. Pregnancy rate to FTAI was significantly higher (P=0.0051) in cows trated with Fertagy (13.4%) than the pregnancy rate to FTAI to cows trated with saline (17.8%). The effectiveness of gunadorelin for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in beef cows was demonstrated in a field study at 10 different locations in the U.S. A total of 306 locations are distingent or multiparous beef cows within 40-150 days postpartum were enrolled in the study. A total of 304 cows were administered gonadorelin a througe in whice in the following excettae sali and 322 cows were administered an equivalent volume of water for injections as nitrinamuscular injection wice in the following regimen: Day 0: 100 mcg gonadorelin (as the acetate salt) or sterile water for injection Day 7: 500 mcg cloprostenol (as cloprostenol sodium)

Day 7: 500 meg Coprostenol (as cloprostenol sodium) Day 8: 100 meg Coprostenol (as cloprostenol sodium) Day 8: 100 meg Coprostenol (as the acetate salt) or sterile water for injection Fixed time Al was performed inmediately after the Day 9 injection. Cows were evaluated for pregnancy on Day 55±5 days by trans-rectal utrasound. Pregnancy rate to FTAI was significantly higher (P=0.0006) in cows treated with gonadorelin (21.7%) than the pregnancy rate to FTAI in cows treated with water (7.4%).

In corst acated with wear (7-4); The effectiveness of a 2-mL docs of gonadorelin delivering 86 mcg gonadorelin (as gonadorelin acetate) for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in lactating dairy cows and beef cows was also demonstrated through references to scientific rature

HOW SUPPLIED: Fertagyl is availa and dibasic). lable in a concentration of 43 mcg/mL gonadorelin (as gonadorelin acetate) pH adjusted with sodium phosphate (monobasi

a vontrauct, mANULING, AND DISPOSAL Keep refrigerated: 2"-8"C (35"-46"F).
 20 mL viai: Use within 28 days of first puncture.
 100 mL viai: Use within 28 days of first puncture and puncture a maximum of 10 times when using an 18 gauge needle. When using a draw-off spike or needle with bore diameter larger than 18 gauge, discard any product remaining in the vial immediately after use.
 Approved by FDA under ANADA # 200-134

factured for: et Inc. (d/b/a Merck Animal Health)

Madison, NJ 07940

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