

# CYSTORELIN. The trusted and effective GnRH.

# Ask for The Original.

CYSTORELIN was the first GnRH approved by the FDA for the treatment of cystic ovaries in cattle. Millions of calves later, it's still the trusted favorite among veterinarians and dairy producers, and the industry standard by which all GnRH products are measured.



# Help cows conceive and calve on schedule.

Veterinarians and dairy producers use CYSTORELIN to treat ovarian follicular cysts, thereby activating the process leading to estrus (heat). As a result, more cows conceive and calve on schedule. CYSTORELIN helps reduce days open and calving intervals.

## Easy to use.

- Intramuscular (IM) or intravenous administration
- 2 mL dose
- No milk withholding

# Veterinarian prescription required.

- Available in 5-dose bottles (10 mL per bottle)
- One case includes twenty 5-dose bottles (100 doses per case)





## CYSTORELIN®

(gonadorelin diacetate tetrahydrate)

#### FOR INJECTION

For the treatment of cystic ovaries in cattle.

#### DESCRIPTION:

CYSTORELIN is a sterile solution containing 50 micrograms of gonadorelin (GnRH) diacetate tetrahydrate per milliliter suitable for intramuscular or intravenous administration. 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  $C_{55}H_{75}N_{17}O_{13}$ . The diacetate tetrahydrate ester has a molecular weight of 1374.48 and empirical formula of  $C_{59}H_{91}N_{17}O_{21}$ .

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 and/or released from the hypothalamus during various stages of the bovine estrus 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 diacetate tetrahydrate has been shown to be safe. The  ${\rm LD}_{\rm 50}$  for mice and rats is

greater than 60 mg/kg, and for dogs greater than 600 mcg/kg, respectively. No untoward effects were noted among rats or dogs administered 120 mcg/kg/day or 72 mcg/kg/day intravenously for 15 days.

It has 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 of gonadorelin diacetate tetrahydrate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects.

The intramuscular administration of 1000 mcg to normally cycling dairy cattle had no effect on hematology or blood chemistry.

Further, CYSTORELIN does not cause irritation at the site of intramuscular administration in dogs. The dosage administered was 72 mcg/kg/day for seven (7) days.

## INDICATIONS AND DOSAGE:

CYSTORELIN (gonadorelin diacetate tetrahydrate) 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.

CYSTORELIN initiates release of endogenous LH to cause ovulation and luteinization.

The recommended intravenous or intramuscular dosage of CYSTORELIN is 100 mcg/cow.

Each mL of CYSTORELIN contains:
Gonadorelin diacetate tetrahydrate50 mcg
Benzyl Alcohol9 mg
Sodium Chloride7.47 mg
Water for Injection, U.S.Pq.s.
pH adjusted with potassium phosphate (monobasic
and dibasic)

#### PRECAUTIONS:

Not for use in humans.

Keep this and all drugs out of reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain an MSDS or for assistance, call 1-888-637-4251.

## KEEP REFRIGERATED: 2° - 8°C (36° - 46°F)

CAUTION: Federal (U.S.A.) law restricts this drug to use by, or on the order of, a licensed veterinarian.

## **HOW SUPPLIED:**

CYSTORELIN is available in a concentration of 50 mcg/mL pH adjusted with potassium phosphate (monobasic and dibasic).

CYSTORELIN is supplied in single vials containing 2 mL of sterile solution and in multi-dose vials containing 10 mL of sterile solution.

Write for additional information about CYSTORELIN.

NADA 098-379, Approved by FDA Marketed by: Merial Limited, Duluth, GA 30096

