



# CYSTORELIN®

(gonadorelin diacetate tetrahydrate)

1050-2907-01

Item No. 82830201

NADA 098-379, Approved by FDA

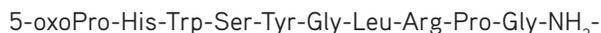
## FOR INJECTION

For the treatment of cystic ovaries in cattle

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

### 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-



a molecular weight of 1182.32 and empirical formula C<sub>55</sub>H<sub>75</sub>N<sub>17</sub>O<sub>13</sub>. The diacetate tetrahydrate ester has a molecular weight of 1374.48 and empirical formula C<sub>59</sub>H<sub>91</sub>N<sub>17</sub>O<sub>21</sub>.

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 LD<sub>50</sub> 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® 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 (2 mL) per cow.

Each mL of CYSTORELIN contains:

Gonadorelin diacetate tetrahydrate .....	50 mcg
Benzyl Alcohol .....	9 mg
Sodium Chloride .....	7.47 mg
Water for Injection, U.S.P. ....	q.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.

**STORAGE CONDITIONS:** Store at or below 77°F (25°C).

Brief excursions to 86°F (30°C) are permitted.

Discard remaining product 6 months after first use.

### HOW SUPPLIED:

CYSTORELIN is available in a concentration of 50 mcg/mL pH adjusted with potassium phosphate (monobasic and dibasic). CYSTORELIN is supplied in multi-dose vials containing 10 mL and 30 mL of sterile solution.

Marketed by:  
Merial Limited  
Duluth, GA 30096-4640 U.S.A.

Technical Support 1-888-637-4251

®CYSTORELIN and the Cattle Head Logo are registered trademarks of Merial.

©2012 Merial. All Rights Reserved.

Rev. 02/2012