

CYSTORELIN® (gonadorelin diacetate tetrahydrate) comes in two sizes.

CYSTORELIN® (gonadorelin diacetate tetrahydrate) viene en dos tamaños.

The 5-dose and 15-dose bottles contain the same trusted formulation of CYSTORELIN.

Las botellas de 5 y 15 dosis contienen la misma formulación confiada de CYSTORELIN.

Each white carton contains one (10 mL) bottle with 5 doses per bottle.

Cada cartón blanco contiene una (10 mL) botella con 5 dosis por botella.



Each blue carton contains 10 (30 mL) bottles with 15 doses per bottle. Total of 10 bottles times 15 doses equals 150 doses per carton.

Cada cartón azul contiene 10 (30 mL) botellas con 15 dosis por botella. Un total de 10 botellas por 15 dosis igual a 150 dosis por cartón.



CYSTORELIN is easy to use.

Animals: For cows
Dosage: 2 mL intramuscular (IM)
Milk withholding: None
Meat withdrawal: None
Refrigeration: Yes

CYSTORELIN es fácil para usar.

Animales: Para vacas
Dosificación: 2 mL vía intramuscular (IM)
Descarte de leche: Ninguno
Tiempo de retiro en carne: Ninguno
Refrigeración: Si

Help herds conceive and calve on schedule.

CYSTORELIN effectively treats ovarian follicular cysts to activate the process leading to estrus.

Ayuda a los hatos a concebir y parir según calendario previsto.

CYSTORELIN trata efectivamente los quistes foliculares ováricos para activar el proceso que conlleva al estro.

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. CYSTORELIN is indicated for the treatment of ovarian follicular cysts in cattle. DO NOT USE IN HUMANS. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

La ley Federal (USA) limita el uso de esta droga por o bajo prescripción de un médico veterinario matriculado. CYSTORELIN esta indicada para el tratamiento de quistes foliculares ováricos en ganado. NO USAR EN HUMANOS. MANTENGA ESTA Y TODAS LAS DROGAS FUERA DEL ALCANCE DE LOS NIÑOS.

CYSTORELIN®.
Millions of calves and counting.

CYSTORELIN®.
Millones de terneros y contando.



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-NH₂

a molecular weight of 1182.32 and empirical formula C₅₅H₇₅N₁₇O₁₃. The diacetate tetrahydrate ester has a molecular weight of 1374.48 and empirical formula of C₅₉H₉₁N₁₇O₂₁.

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 LD₅₀ 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 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.

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

Discard remaining product 90 days after first use.

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 multi-dose vials containing 10 mL and 30 mL of sterile solution.

NADA 098-379, Approved by FDA

Marketed by: Merial Limited, Duluth, GA 30096

