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The Bovine PRACTITIONER

THE OFFICIAL PUBLICATION OF THE
AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS

Moraxella bovoculi Bacterin

World's First Commercially Available Moraxella bovoculi Pinkeye Preventative!

- **8 Different M. bovoculi Isolates**
- **Cost Effective for All Cattle Herds**
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- **More Convenient than Autogenous Programs**

Addison Biological Laboratory, Inc. announces the approval of the world's first commercial Moraxella bovoculi vaccine for the prevention of pinkeye in cattle. This USDA conditionally licensed product is the first of this kind. Previously the only method of prevention against *Moraxella bovoculi* was autogenous services. This vaccine signifies a breakthrough in convenience for the large number of veterinarians and herd owners battling the challenging problem of pinkeye caused by *Moraxella bovoculi*. This product license is conditional; efficacy and potency have not been fully demonstrated.

From the LEADERS in pinkeye prevention!

ADDISON BIOLOGICAL LABORATORY

Addison Biological Laboratory, Inc.
www.addisonlabs.com
info@addisonlabs.com
800-331-2530

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THE BOVINE PRACTITIONER is the official publication of The American Association of Bovine Practitioners, published in the spring and summer annually. It serves as a communication medium between bovine practitioner organizations around the world. All manuscripts and communications must be presented in English. Beginning in 2019, THE BOVINE PRACTITIONER is an open access journal following a 6-month post-publication embargo to allow AABP members and veterinary medical libraries first access.

Copies of THE BOVINE PRACTITIONER are available to non-members for $30.00 per copy for domestic destinations, or $35.00 for international addresses. **Contact editor for details.**

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Conference photos courtesy of Dr. Bob Smith.

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Notice to Readers

All statements, opinions and conclusions contained in articles in *The Bovine Practitioner* are those of the author(s), and are not necessarily those of the American Association of Bovine Practitioners (AABP) unless specifically approved by the AABP Board of Directors.

CONGRATS, IT'S A CALF! AGAIN!

It's easy to be confident that your cows will get pregnant when you use Cystorelin® (gonadorelin) and Synchsure® (cloprostenol sodium) together. They're an effective combination for reproductive efficiency. So, after use, this test is more of a formality.

MAXIMIZE REPRODUCTIVE EFFICIENCY ON YOUR OPERATION AT SYNCTHEHERD.COM.

IMPORTANT SAFETY INFORMATION FOR CYSTORELIN: Do not use in humans. Keep this and all drugs out of the reach of children.

IMPORTANT SAFETY INFORMATION FOR SYNCHSURE: FOR ANIMAL USE ONLY, NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages women may be unaware of their pregnancies. SYNCHSURE is readily absorbed through the skin and may 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.

Boehringer Ingelheim

Cattle First.

CYSTORELIN® (gonadorelin)

SYNCHSURE® (cloprostenol sodium)

CYSTORELIN®

(gonadorelin)

By Merial

For treatment of cystic ovaries in dairy cattle

For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows.

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 43 mcg/mL of gonadorelin (GnRH) as 50 mcg/mL gonadorelin diacetate tetrahydrate 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-NH2—

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 $C_{59}H_{91}N_{17}O_{21}$.
Each mL of CYSTORELIN contains:

Gonadorelin diacetate tetrahydrate (equivalent to 43 mcg gonadorelin)	50 mcg
Benzyl Alcohol	9 mg
Sodium Chloride	7.47 mg
Water for Injection	q.s.

pH adjusted with potassium 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
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 LH such as human chorionic gonadotrophin. CYSTORELIN initiates release of endogenous LH to cause ovulation and luteinization.

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

DOSAGE AND ADMINISTRATION:
Cystic Ovaries
The intravenous or intramuscular dosage of CYSTORELIN is 100 mcg gonadorelin diacetate tetrahydrate (2 mL) per cow.

Reproductive Synchrony
The intramuscular dosage of CYSTORELIN is 100 mcg gonadorelin diacetate tetrahydrate (2 mL) per cow, used in reproductive synchrony programs similar to the following:

1. Administer the first CYSTORELIN injection (2 mL) at Time 0.
2. Administer 500 mcg cloprostenol (as cloprostenol sodium) by intramuscular injection 6 to 8 days after the first CYSTORELIN injection.
3. Administer the second CYSTORELIN injection (2 mL) 30 to 72 hours after the cloprostenol sodium injection.
4. Perform FTAI 0 to 24 hours after the second CYSTORELIN 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.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To obtain a SDS or for technical assistance, contact Merial at 1-888-637-4251. To report suspected adverse drug experiences, contact Merial at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary.

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 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 of gonadorelin diacetate tetrahydrate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects. Further, CYSTORELIN 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 CYSTORELIN was established through the review and evaluation of the extensive published literature available for the use of gonadorelin-containing products.

The intramuscular administration of 1000 mcg gonadorelin diacetate tetrahydrate 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 CYSTORELIN for the treatment of ovarian follicular cysts, the incidence of health abnormalities was not significantly greater in cows administered CYSTORELIN 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. The incidence of health abnormalities was not significantly greater in cows administered gonadorelin than cows administered a placebo injection.

EFFECTIVENESS:
The use of CYSTORELIN for treatment of ovarian follicular cysts in dairy cattle was demonstrated to be effective with a treatment dose of 100 mcg gonadorelin diacetate tetrahydrate.
The effectiveness of gonadorelin for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in lactating dairy cows was demonstrated in a field study at 10 different locations in the U.S. Four of the locations represented conditions that would typically cause heat stress in lactating cows. A total of 1607 healthy, non-pregnant, primiparous or multiparous lactating dairy cows within 40-150 days postpartum were enrolled in the study. A total of 805 cows were administered gonadorelin (1 mL; 100 mcg gonadorelin as the acetate salt) and 802 cows were administered an equivalent volume of water for injection as an intramuscular injection twice in the following regimen:
Day 0: 100mcg gonadorelin (as the acetate salt) or sterile water for injection
Day 7: 500 mcg cloprostenol (as cloprostenol sodium)
Day 9: 100mcg gonadorelin (as the acetate salt) or sterile water for injection
Fixed time AI was performed on Day 10, approximately 11 - 31 hours after the Day 9 injection. Cows were evaluated for pregnancy on Day 45 ± 5 days by trans-rectal ultrasound or rectal palpation. Pregnancy rate to FTAI was significantly higher ($P < 0.0001$) in cows treated with gonadorelin (33.4%) than the pregnancy rate to FTAI in cows treated with water (13.6%). The environmental condition (heat stress or not heat stress) did not affect the conclusion of effectiveness. The effectiveness of gonadorelin 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 706 healthy, non-pregnant, primiparous or multiparous beef cows within 40-150 days postpartum were enrolled in the study. A total of 364 cows were administered gonadorelin (1 mL; 100 mcg gonadorelin as the acetate salt) and 342 cows were administered an equivalent volume of water for injection as an intramuscular injection twice in the following regimen:
Day 0: 100mcg gonadorelin (as the acetate salt) or sterile water for injection
Day 7: 500 mcg cloprostenol (as cloprostenol sodium)
Day 9: 100mcg gonadorelin (as the acetate salt) or sterile water for injection
Fixed time AI was performed immediately after the Day 9 injection. Cows were evaluated for pregnancy on Day 55 ± 5 days by trans-rectal ultrasound. 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%).

The effectiveness of a 2-mL dose of CYSTORELIN delivering 100 mcg gonadorelin diacetate tetrahydrate (86 mcg gonadorelin) 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 literature.

HOW SUPPLIED:
CYSTORELIN is available in a concentration of 50 mcg/mL gonadorelin diacetate tetrahydrate (43 mcg/mL gonadorelin) pH adjusted with potassium phosphate (monobasic and dibasic).

CYSTORELIN is supplied in multi-dose vials containing 10 mL and 30 mL of sterile solution.

STORAGE, HANDLING, AND DISPOSAL: Store at or below 77°F (25°C). Brief excursions to 86°F (30°C) are permitted. Use within 6 months of first puncture.

NADA 098-379, Approved by FDA

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

SYNCHSURE™

(cloprostenol sodium)

By Merial

Prostaglandin Analogue for Cattle
Equivalent to 250 mcg cloprostenol/mL

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

DESCRIPTION:
SYNCHSURE (cloprostenol sodium) is a synthetic prostaglandin analogue related to prostaglandin $F_{2\alpha}$. SYNCHSURE is indicated for intramuscular use at a two mL dose to induce luteolysis in beef and dairy cattle. The luteolytic action of SYNCHSURE can be used to manipulate the estrous cycle to better fit certain management practices, to terminate pregnancies resulting from mismatings, and to treat certain conditions associated with prolonged luteal function.

USES OF SYNCHSURE:
Unobserved or Nondetected Estrus: If a mature ***corpus luteum*** is present, SYNCHSURE can be used to induce estrus. Estrus is expected to occur 2 to 5 days following injection. Treated cattle should be inseminated at the usual time following detected estrus or twice at 72 and 96 hours post injection if estrus detection is not possible or desirable.

Pyometra or Chronic Endometritis: Endometritis is inflammation of the uterus and pyometra is characterized by the lack of cyclical estrus behavior and the presence of a persistent ***corpus luteum***. SYNCHSURE induces luteolysis which usually results in evacuation of the uterus and a return to normal cycling activity within 14 days after treatment.

Mummified fetus: Induction of luteolysis with SYNCHSURE usually results in the expulsion of the mummified fetus from the uterus. (Manual assistance may be necessary to remove the fetus from the vagina). Normal cyclical activity usually follows.

Luteal Cysts: Luteal cysts may cause abnormal cycling patterns in cows. Treatment with SYNCHSURE can restore normal ovarian activity by causing regression of the luteal cyst.

Pregnancies from mismating: SYNCHSURE can be used to terminate unwanted pregnancies in cattle 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 4 to 5 days after the injection. The efficacy of SYNCHSURE in inducing abortion decreases after 5 months of gestation, while the risk of dystocia and additional consequences increases.

Controlled Breeding: SYNCHSURE can be used to schedule estrus and ovulation for individual animals or a group of animals to control breeding times. SYNCHSURE can be used in controlled breeding programs through either single or double injection protocols. Only animals with a mature ***corpus luteum*** should be treated with the single injection protocol to obtain a maximum response to the single injection. Prior to treatment, cattle should be examined rectally and found to be anatomically normal and nonpregnant. Before a controlled breeding program is planned, the producer and his consulting veterinarian should review the operation's breeding history, herd health and nutritional status and agree that a controlled breeding program is practical in that particular situation.

The use information provided here is not comprehensive. Talk to your veterinarian and consult the full prescribing information available at www.synchsure.com for further details on uses of SYNCHSURE.

SAFETY AND TOXICITY: AT 50 and 100 times the recommended dose, mild side effects may be detected in some cattle including increased uneasiness, slight frothing, and milk let-down. The risk information provided here is not comprehensive. To learn more, talk to your veterinarian about SYNCHSURE or call 1-888-637-4251. The full prescribing information can be found at www.synchsure.com.

CONTRAINDICATIONS: SYNCHSURE should not be given to pregnant animals whose calf is not meant to be aborted.

WARNINGS: For animal use only. Do not use in humans. Keep out of reach of Children. Women of childbearing age, asthmatics and persons with respiratory problems should exercise extreme caution with handling this product. In early stages, women may not be aware of their pregnancies. SYNCHSURE is readily absorbed through the skin and may cause abortion and/or bronchiospasms: direct contact with the skin should be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

PRECAUTIONS:
Careful aseptic techniques should be employed to decrease the possibility of post-injection bacterial infection. Antibiotic therapy should be employed at the first sign of infection. The Safety Data Sheet (SDS) contains more detailed occupational safety information. For technical assistance, to request an SDS, or to report a suspected adverse event, contact Merial Technical Support at 1-888-637-4251. For additional information about adverse event reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary.

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