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 structurally related to prostaglandin F₂α (PGF₂α). Each mL of the colorless aqueous solution contains 263 mcg of cloprostenol sodium (equivalent to 250 mcg of cloprostenol), chlorocresol 1.0 mg as a bactericide, citric acid anhydrous 0.66 mg, sodium citrate 5.02 mg, sodium chloride 6.76 mg. The pH is adjusted, as necessary, with sodium hydroxide or citric acid.

ACTION:

SYNCHSURE causes functional and morphological regression of the corpus luteum (luteolysis) in cattle. In normal, nonpregnant cycling animals, this effect on the life span of the corpus luteum usually results in estrus 2 to 5 days after treatment. In animals with prolonged luteal function (pyometra, mummified fetus, and luteal cysts), the induced luteolysis usually results in resolution of the condition and return to normal cyclicity. The luteolytic action of SYNCHSURE can be utilized to schedule the cyclicity status of the herd before SYNCHSURE treatment. Prior to treatment, cattle should be examined rectally and found to be anatomically normal, nonpregnant, and have a mature corpus luteum. SYNCHSURE has not been sufficiently tested under feedlot conditions; therefore recommendations cannot be made for its use in heifers placed in feedlots.

Controlled Breeding

The luteolytic action of SYNCHSURE can be utilized to schedule the time of estrus and ovulation in a group of animals. This allows control of the time at which cycling cows or heifers can be bred. SYNCHSURE can be incorporated into a controlled breeding program by the following methods:

1. Single SYNCHSURE 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, nonpregnant, 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 estrus detection is not desirable or possible, treated animals may be inseminated twice at about 72 and 96 hours postinjection.

2. Double SYNCHSURE Injections

Prior to treatment, cattle should be examined rectally and found to be anatomically normal, nonpregnant, and cycling (the presence of a mature corpus 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 cattle, estrus is expected to 2 to 5 days following the second injection. Treated cattle should be inseminated at the usual time following detection of estrus. If estrus detection is not desirable or possible, treated animals may be inseminated either once at about 72 hours or twice at about 72 and 96 hours following the second SYNCHSURE injection.

Any controlled breeding program recommended should be completed by either:

- observing animals (especially during the third week after injection) and inseminating or hand mating any animals returning to estrus,
- turning in cleanup bulls 5 to 7 days after the last injection of SYNCHSURE to cover any animals returning to estrus.

REQUIREMENTS FOR CONTROLLED BREEDING PROGRAMS:

A variety of programs can be designed to best meet the needs and objectives of the individual management system. A controlled breeding program should be selected which is appropriate for the existing circumstances and management practices.

Before a controlled breeding program is planned, the producer’s objectives must be examined and he must be made aware of the projected results and limitations. The producer and his consultant should review the operator’s breeding history, herd health and nutritional status and agree that a controlled breeding program is practical in the producer’s specific situation. For any successful controlled breeding program:

- cows and heifers must be normal, nonpregnant, and cycling (rectal palpation should be performed),
- cattle must be in a fit and thirsty breeding 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.

Pyometra or Chronic Endometritis

Damage to the reproductive tract at calving or postpartum retention of the placenta often leads to infection and inflammation of the uterus (endometritis). Under certain circumstances, this may progress into chronic endometritis with the uterus becoming distended with purulent matter. This condition, commonly referred to as pyometra, is characterized by a lack of cyclical estrus behavior and the presence of a persistent corpus luteum. Induction of luteolysis with SYNCHSURE usually results in evacuation of the uterus and a return to normal cyclical activity within 14 days after treatment. After 14 days posttreatment, the recovery rate of treated animals will not be different than that of untreated cattle.

Mummified Fetus

Death of the conceptus during gestation may be followed by its degeneration and dehydration. Induction of luteolysis with SYNCHSURE usually results in 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

A cow may be noncyclic due to the presence of a luteal cyst (a single, anovulatory follicle with a thickened wall which is accompanied by no external signs and by no changes in palpable consistency of the uterus). Treatment with SYNCHSURE can restore normal ovarian activity by causing regression of the cystic wall.

Pregnancies from Mismating

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 SYNCHSURE to induce abortion decreases beyond the fifth month of gestation.

Death of the conceptus during gestation may be followed by its degeneration and dehydration. Induction of luteolysis with SYNCHSURE usually results in estrus 2 to 5 days after the injection with the reproductive tract returning to normal soon after the abortion.

It is important to understand that SYNCHSURE is effective in reducing the condition of an acute pyometra (ovulation must have occurred at least 5 days prior to treatment). This must be considered when breeding is intended following a single SYNCHSURE injection.

SAFETY AND TOXICITY:

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.

CONTRAINDICATIONS:

SYNCHSURE should not be administered to a pregnant animal whose call is not to be aborted.

WARNINGS:

For animal use only.

Women of childbearing 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.

PRECAUTIONS:

There is no effect on fertility following the single or double dosage regimen when breeding occurs at induced estrus or at 72 and 96 hours posttreatment. Conception rates may be lower than expected in those fixed time breeding programs which omit the second insemination (i.e. the insemination at or near 96 hours). This is especially true if a fixed time insemination is used following a single SYNCHSURE injection.

As with all parental products, careful aseptic techniques should be employed to decrease the possibility of postinsemination bacterial infection. Antibiotic therapy should be employed at the first sign of infection.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To obtain an MSDS or for technical assistance, contact Merial Technical Support at 1-888-637-4251. To report suspected adverse drug experiences, contact Merial Technical Support 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.

DOSAGE AND ADMINISTRATION:

Two mL of SYNCHSURE (500 mcg of cloprostenol) should be administered by INTRAMUSCULAR INJECTION for all indications in both beef and dairy cattle. Discard remaining product 180 days after first use.

STORAGE CONDITIONS:

1. Protect from light.

2. Store in carton.


HOW SUPPLIED:

100mL multidose vial

Made in Australia

Distributed by:

Merial, Inc.

3239 Satellite Boulevard

Duluth, GA 30096

ANADA 200-310. Approved by FDA

100mL 50331b-01

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