

CHRONOMATE- altrenogest solution
Ceva Santé Animale

ChronoMate™

(altrenogest)

SOLUTION 0.22%

(2.2 mg/mL)

FOR ORAL USE IN ANIMALS ONLY

Drug Facts:

Active ingredients: Altrenogest Solution 0.22% (2.2 mg/mL)

Use: For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle. Treatment with altrenogest solution 0.22% results in estrus (standing heat) 4 to 9 days after completion of the 14-day treatment period.

Caution: Federal law prohibits extra-label use of this drug to enhance food and/or fiber production in animals.

Do Not Use: In gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis).

WARNINGS

Keep this and all medication out of the reach of children.

User/Handler Safety: Avoid skin contact. Wear vinyl, neoprene or nitrile protective gloves when handling this product. **DO NOT USE LATEX GLOVES**

Pregnant women or women who suspect they are pregnant should not handle ChronoMate (altrenogest) solution 0.22%. Women of childbearing age should exercise extreme caution when handling this product. Accidental absorption could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Wash off accidental spillage on the skin immediately with soap and water.

People who should not handle this product:

1. Women who are or suspect they are pregnant.
2. Anyone with thrombophlebitis or thromboembolic disorders or with a history of these events.
3. Anyone with cerebral-vascular or coronary-artery disease.
4. Women with known or suspected carcinoma of the breast.
5. People with known or suspected estrogen-dependent neoplasia.
6. Women with undiagnosed vaginal bleeding.
7. People with benign or malignant tumors which developed during the use of oral contraceptives or other estrogen-containing products.
8. Anyone with liver dysfunction or disease.

Accidental exposure: Altrenogest is readily absorbed from contact with the skin. In addition, this oil based product can penetrate porous gloves. Altrenogest should not penetrate intact vinyl, neoprene or nitrile protective gloves; however, if there is leakage (i.e., pinhole, spillage, etc.) the contaminated area covered by such occlusive materials may have increased absorption. **DO NOT USE LATEX GLOVES**

The following measures are recommended in case of accidental exposure.

Skin Exposure: Wash immediately with soap and water.

Eye Exposure: Immediately flush with plenty of water for 15 minutes. Get medical attention.

If Swallowed: Do not induce vomiting. ChronoMate (altrenogest) solution 0.22% contains an oil. Call a physician. Vomiting should be supervised by a physician because of possible pulmonary damage via aspiration of the oil base. If possible, bring the container and labeling to the physician.

Effects of Overexposure: There has been no human use of this specific product. The information contained in this section is extrapolated from data available on other products of the same pharmacological class that have been used in humans. Effects anticipated are due to the progestational activity of altrenogest. Acute effects after a single exposure are possible; however, continued daily exposure has the potential for more untoward effects such as disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy and headaches. The oil base may also cause complications if swallowed. In addition, the list of people who should not handle this product is based upon the known effects of progestins used in humans on a chronic basis.

Human Food Safety: Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

Environmental Safety: Place empty drug containers and used syringes, protective gloves or other articles that come in contact with this product in a leak-resistant container for disposal in accordance with applicable Federal, state and local regulations.

Adverse Reactions and Potential Safety Hazards: Underfeeding of ChronoMate may lead to the occurrence of cystic follicles.

When Using This Product: A small percentage (less than 5%) of treated gilts may exhibit estrus (standing heat) during the 14-day treatment period. Gilts nearing estrus at the start of the 14-day treatment period may express estrus early in that period.

Dosage and Directions: While wearing protective gloves, remove shipping cap and seal; replace with enclosed plastic dispensing cap. Remove cover from bottle dispensing tip and connect luer lock syringe (without needle). Draw out appropriate volume of ChronoMate. (Note: Do not remove syringe while bottle is inverted as spillage may result.) Detach syringe and replace cover on bottle dispensing tip to prevent leakage. Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days. Treat gilts on an individual animal basis by top-dressing ChronoMate on a portion of each gilt's daily feed allowance. To produce the desired synchronization of estrus in a group of gilts, treat all of the gilts daily for the same 14-day period. Excessive use of a syringe may cause the syringe to stick; therefore, replace syringe as necessary.

Other Information:

Storage: Store at or below room temperature, 77°F (25°C). Close tightly.

Questions? Comments?

- To report a suspected adverse reaction, call 1-800-999-0297.
- To obtain product information, including material safety data sheet (MSDS), call 1-800-999-0297.

Manufactured for:

Ceva Santé Animale, Libourne, France

Marketed by:

Ceva Animal Health, LLC Lenexa, KS 66215

ANADA # 200-579, Approved by FDA

PRINCIPAL DISPLAY PANEL - 1000 mL BOTTLE

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Net Contents: 1000 mL

Restricted Drug (California) – use only as directed.

Not for Human Use

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(altrenogest)

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LIFT front label for full directions for use and warnings.

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Close tightly.

ChronoMate trademark is the property of Ceva Santé Animale S.A.
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Manufactured for:
Ceva Santé Animale
Libourne, France

Marketed by:
Ceva Animal Health, LLC
Lenexa, KS 66215

ANADA #200-579. Approved by FDA
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Lot/Exp:

CEVA

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CEVA **LIFT**

CHRONOMATE

altrenogest solution

Product Information

| | | | |
|--------------------------------|-----------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:13744-520 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALTRENOGEST (UNII: 2U0X0JA2NB) (ALTRENOGEST - UNII:2U0X0JA2NB) | ALTRENOGEST | 2.2 mg in 1 mL |

Product Characteristics

| | | | |
|----------|----------------|--------------|--|
| Color | YELLOW (Light) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13744-520-10 | 1000 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200579 | 01/18/2016 | |

Labeler - Ceva Santé Animale (261126049)

Revised: 2/2016

Ceva Santé Animale