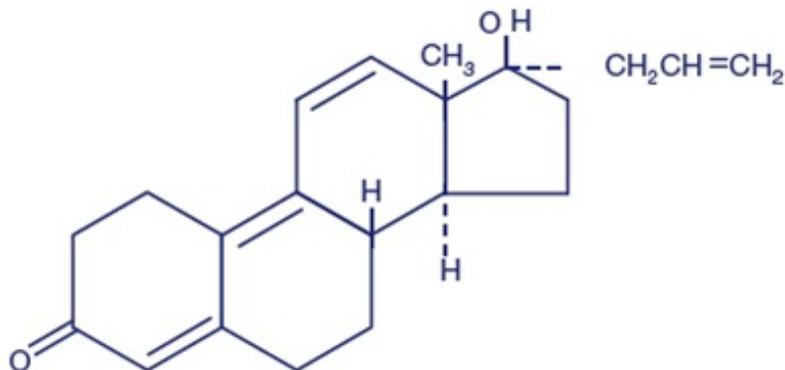


**ALTRESYN- altrenogest solution**  
**Ceva Santé Animale**

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**Altresyn® (altrenogest)**

**DESCRIPTION**

ALTRESYN (altrenogest) Solution 0.22% contains the active synthetic progestin, altrenogest. The chemical name is 17 $\alpha$ -allyl-17 $\beta$ -hydroxyestra-4,9,11-trien-3-one. The CAS Registry Number is 850-52-2. The chemical structure is:



Each mL of ALTRESYN® (altrenogest) Solution 0.22% contains 2.2 mg of altrenogest in an oil solution.

**ACTIONS:** ALTRESYN (altrenogest) Solution 0.22% produces a progestational effect in mares.

**INDICATIONS AND USAGE**

ALTRESYN (altrenogest) Solution 0.22% is indicated to suppress estrus in mares. Suppression of estrus allows for a predictable occurrence of estrus following drug withdrawal. This facilitates the attainment of regular cyclicity during the transition from winter anestrus to the physiological breeding season. Suppression of estrus will also facilitate management of prolonged estrus conditions. Suppression of estrus may be used to facilitate scheduled breeding during the physiological breeding season.

**CONTRAINDICATIONS**

ALTRESYN (altrenogest) Solution 0.22% is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or “smoldering” uterine inflammation into a fulminating uterine infection in some instances.

**WARNINGS**

**For oral use in horses only. Keep this and all other medications out of the reach of children. Do not use in horses intended for human consumption.**

**HUMAN WARNINGS: Skin contact must be avoided as ALTRESYN® (altrenogest) Solution 0.22% is readily absorbed through unbroken skin. Protective gloves must be worn by all persons handling this product. Pregnant women or women who suspect they are pregnant should not**

**handle ALTRESYN (altrenogest) Solution 0.22%. Women of child bearing age should exercise extreme caution when handling this product. Accidental absorption could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.**

#### **INFORMATION FOR HANDLERS:**

**WARNING: ALTRESYN (altrenogest) Solution 0.22% is readily absorbed by the skin. Skin contact must be avoided; protective gloves must be worn when handling this product.**

**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 (see at top of next column) is based upon the known effects of progestins used in humans on a chronic basis.

#### **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 rubber or impervious gloves; however, if there is leakage (i.e., pinhole, spillage, etc.), the contaminated area covered by such occlusive materials may have increased absorption. 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. ALTRESYN (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.

**Store at or below 25° C (77° F).**

#### **PRECAUTIONS**

Various synthetic progestins, including altrenogest, when administered to rats during the embryogenic stage of pregnancy at doses manyfold greater than the recommended equine dose caused fetal

anomalies, specifically masculinization of the female genitalia.

## **DOSAGE AND ADMINISTRATION**

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 ALTRESYN solution. (Note: Do not remove syringe while bottle is inverted as spillage may result.) Detach syringe and administer solution orally at the rate of 1mL per 110 pounds body weight (0.044 mg/kg) once daily for 15 consecutive days. Administer solution directly on the base of the mare's tongue or on the mare's usual grain ration. Replace cover on bottle dispensing tip to prevent leakage. Excessive use of a syringe may cause the syringe to stick; therefore, replace syringe as necessary.

## **DOSAGE CHART:**

<b>Approximate Weight in Pounds</b>	<b>Dose in mL</b>
<b>770</b>	<b>7</b>
<b>880</b>	<b>8</b>
<b>990</b>	<b>9</b>
<b>1100</b>	<b>10</b>
<b>1210</b>	<b>11</b>
<b>1320</b>	<b>12</b>

## **WHICH MARES WILL RESPOND TO ALTRESYN (altrenogest)**

**SOLUTION 0.22%:** Extensive clinical trials have demonstrated that estrus will be suppressed in approximately 95% of the mares within three days; however, the post-treatment response depended on the level of ovarian activity when treatment was initiated. Estrus in mares exhibiting regular estrus cycles during the breeding season will be suppressed during treatment; these mares return to estrus four to five days following treatment and continue to cycle normally. Mares in winter anestrus with small follicles continued in anestrus and failed to exhibit normal estrus following withdrawal.

Response in mares in the transition phase between winter anestrus and the summer breeding season depended on the degree of follicular activity. Mares with inactive ovaries and small follicles failed to respond with normal cycles post-treatment, whereas a higher proportion of mares with ovarian follicles 20 mm or greater in diameter exhibited normal estrus cycles post-treatment. Altrenogest solution 0.22% was very effective for suppressing the prolonged estrus behavior frequently observed in mares during the transition period (February, March and April). In addition, a high proportion of these mares responded with regular estrus cycles post-treatment

## **HOW SUPPLIED**

ALTRESYN (altrenogest) Solution 0.22% (2.2 mg/mL). Each mL contains 2.2 mg altrenogest in an oil solution. Available in 1000 mL plastic bottles.

**Manufactured for:** Ceva Sante Animale, Libourne, France

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

MADE IN USA ANADA # 200-481, Approved by FDA

Product: D551US / Component: 01-A1-v1

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Altresyn® (altrenogest)  
1000 mL

Oral Progestin

**For Use in Animals Only**

**Solution 0.22% (2.2 mg/mL)**

**For suppression of estrus in mares.**

Suppression of estrus allows for a predictable occurrence of estrus following drug withdrawal in mares with ovarian follicles 20 mm or greater.

Suppression of estrus will facilitate:

Attainment of regular cyclicity during the transition from winter anestrus to the physiological breeding season.

Management of prolonged estrus conditions.

Scheduled breeding during the physiological breeding season.

**For Oral Use in Horses Only**

**Warning: Do Not Use in Horses Intended for Human Consumption.**

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

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

**Manufactured for:** Ceva Sante Animale, Libourne, France

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

C68410B

Store at or below 25°C (77°F)

Reclose tightly.

MADE IN USA

**Altresyn®**  
(altrenogest)

**WARNING:** Skin contact must be avoided as Altresyn® is readily absorbed through unbroken skin. Protective gloves must be worn by all persons handling this product. Pregnant women or women who suspect they are pregnant should not handle Altresyn. 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. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

**CONTRAINDICATIONS:** Altresyn (altrenogest) Solution 0.22% is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or "smoldering" uterine inflammation into a fulminating uterine infection in some instances.

**DOSAGE:** Each mL of Altresyn contains 2.2 mg of altrenogest in an oil solution. Administer orally at the rate of 1 mL per 110 pounds body weight (0.044 mg / kg). To be given one dose daily for 15 consecutive days.

**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 Altresyn® solution. **(Note: Do not remove syringe while bottle is inverted as spillage may result.)** Detach syringe and administer solution directly on the base of the mare's tongue or on the mare's usual grain ration. Replace cover on bottle dispensing tip to prevent leakage. Excessive use of a syringe may cause the syringe to stick; therefore, replace syringe as necessary.

Refer to package insert for full directions for use, precautions and warnings.

ANADA #200-481, Approved by FDA

**Manufactured for:**  
Ceva Sante Animale  
Libourne, France

**Marketed by:**  
Ceva Animal Health, LLC  
Lenexa, KS 66215  
C68410B  
Store at or below 25°C (77°F)  
Reclose tightly.

MADE IN USA

Lot/Exp:

**Altresyn®**  
(altrenogest)  
1000 mL

**ORAL PROGESTIN  
FOR USE IN ANIMALS ONLY**  
**SOLUTION 0.22% (2.2 mg/mL)**  
**For suppression of estrus in mares.**

Suppression of estrus allows for a predictable occurrence of estrus following drug withdrawal in mares with ovarian follicles 20 mm or greater.

Suppression of estrus will facilitate:

- Attainment of regular cyclicity during the transition from winter anestrus to the physiological breeding season.
- Management of prolonged estrus conditions.
- Scheduled breeding during the physiological breeding season.

**FOR ORAL USE IN HORSES ONLY**  
**WARNING: DO NOT USE IN HORSES INTENDED FOR HUMAN CONSUMPTION.**

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

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

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## Carton Label

### ALTRESYN

altrenogest solution

#### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG LABEL	<b>Item Code (Source)</b>	NDC:13744-500
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

#### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALTRENOGEST (ALTRENOGEST)	ALTRENOGEST	2.2 mg in 1 mL

#### Product Characteristics

<b>Color</b>	YELLOW (Light)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

#### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:13744-500-10	1000 mL in 1 BOTTLE		

#### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANADA	ANADA200481	10/12/2012	

**Labeler** - Ceva Santé Animale (261126049)

Revised: 8/2012

Ceva Santé Animale