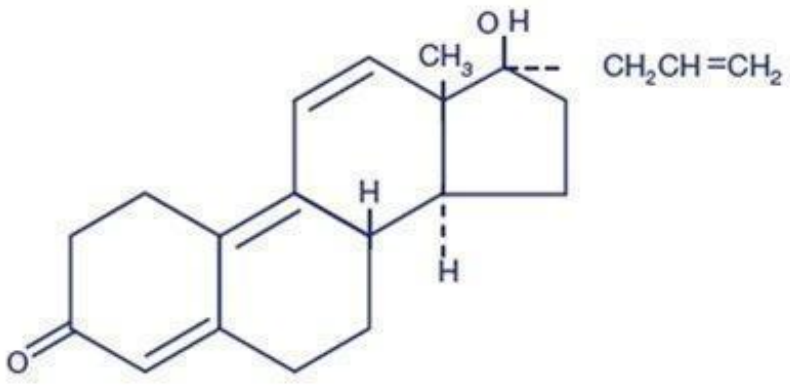
OVAMED- altrenogest solution
Bimeda, Inc.

OvaMed®
(altrenogest)
2.2 mg altrenogest per mL (0.22%)
Oral Solution for Horses

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

DESCRIPTION:
OvaMed (altrenogest) contains the active synthetic progestin, altrenogest. The chemical name is 17a-allyl-17b-hydroxyestra-4,9,11-trien-3-one. The CAS Registry Number is 850-52-2. The chemical structure is:



Each mL of OvaMed (altrenogest) contains 2.2 mg of altrenogest in an oil solution. OvaMed (altrenogest) produces a progestational effect in mares.

INDICATIONS:
For suppression of 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.

DOSAGE AND ADMINISTRATION:
Administer solution orally at the rate of 1 mL 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.

DOSAGE CHART:

Approximate Weight in Pounds	Dose in mL
770	7
880	8
990	9

1100	**10**
1210	**11**
1320	**12**

When handing OvaMed product or syringe, **always use vinyl, neoprene, or nitrile gloves. Latex gloves are not protective.** This product may be dosed using a luer lock syringe.

For use with a luer lock syringe, 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 OvaMed solution and return bottle to upright position before detaching syringe. (Note: Do not remove syringe while bottle is inverted as spillage may result.) Replace cover on bottle dispensing tip to prevent leakage. Syringes used for administration should be replaced frequently and disposed of in a secure manner to prevent exposure to the product.

Which Mares Will Respond to OvaMed: 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

Specific Uses for OvaMed:
1. Suppression of estrus to facilitate attainment of regular cycles during the transition period from winter anestrus to the physiological breeding season. To facilitate attainment of regular cycles during the transition phase, mares should be examined to determine the degree of ovarian activity. Estrus in mares with inactive ovaries (no follicles greater than 20 mm in diameter) will be suppressed, but these mares may not begin regular cycles following treatment. However, mares with active ovaries (follicles greater than 20 mm in diameter) frequently respond with regular post-treatment estrus cycles.
2. Suppression of estrus to facilitate management of the mare exhibiting prolonged estrus during the transition period. Estrus will be suppressed in mares exhibiting prolonged behavioral estrus either early or late during the transition period. Again, the post-treatment response depends on the level of ovarian activity. The mares with greater ovarian activity initiate regular cycles and conceive sooner than the inactive mares. OvaMed (altrenogest) may be administered early in the transition period to suppress estrus in mares with inactive ovaries to aid in the management of these mares or to mares later in the transition period with active ovaries to prepare and schedule the mare, for breeding.

3. Suppression of estrus to permit scheduled breeding of mares during the physiological breeding season. To permit scheduled breeding, mares which are regularly cycling or which have active ovarian function should be given OvaMed (altrenogest) daily for 15 consecutive days beginning 20 days before the date of the planned estrus. Ovulation will occur 5 to 7 days following the onset of estrus as expected for non-treated mares. Breeding should follow usual procedures for mares in estrus. Mares may be regulated and scheduled either individually or in groups.

CONTRAINDICATIONS:
Do not use OvaMed (altrenogest) in mares having a previous or current history of uterine inflammation (e.g., 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 AND PRECAUTIONS:
User Safety Warnings:
Not for use in humans. Keep out of reach of children. Avoid skin contact. OvaMed is absorbed through unbroken skin, and exposure may result in serious side effects to both women and men. **Wear vinyl, neoprene, or nitrile gloves when handling or administering OvaMed, or when touching contaminated surfaces or equipment. Latex gloves are not protective.**
PREGNANT WOMEN OR WOMEN WHO MAY BE PREGNANT SHOULD NOT HANDLE OVAMED. WOMEN OF CHILDBEARING AGE SHOULD EXERCISE EXTREME CAUTION WHEN HANDLING THIS PRODUCT.
Accidental absorption, such as via direct contact with the skin, could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Immediately wash off accidental spillage on the skin with soap and water. Any equipment or surfaces that come in contact with OvaMed should be adequately cleaned and decontaminated to prevent human exposure *(see Reported HUMAN Effects from Exposure)*.

Potential Effects of Human Exposure:
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. The list of people who should not handle this product (see below is based upon the known effects of progestins used in humans on a chronic basis.

PEOPLE WHO SHOULD NOT HANDLE OVAMED:
1. Women who are or may be pregnant.
2. Anyone with blood clots or clotting disorders, or with a history of these events.
3. Anyone with a history of heart disease or stroke.
4. Women with known or suspected breast cancer.
5. People with known or suspected estrogen-dependent cancer.
6. Women with vaginal bleeding of unknown cause.
7. People with tumors which developed during the use of oral contraceptives or other estrogen-containing products.
8. Anyone with liver dysfunction or disease.

ACCIDENTAL EXPOSURE:
OvaMed is readily absorbed through the skin. In addition, this oil based product can penetrate latex or other types of porous gloves. **Always wear vinyl, neoprene, or nitrile gloves when handling or administering OvaMed. Latex gloves are not protective.** If OvaMed gets inside gloves by damage or spilling, the covered skin may absorb more of the drug.

IN CASE OF ACCIDENTAL EXPOSURE:
Skin Exposure and/or clothing contamination: Wash skin immediately with soap and water, and launder clothing with detergent.
Eye Exposure: Immediately flush with plenty of water for 15 minutes. Get medical attention. If wearing contact lenses, flush eyes immediately with water before removing lenses.
If Swallowed: Do not induce vomiting. Seek medical attention immediately. OvaMed contains an oil. Vomiting should be supervised by a physician because of possible pulmonary damage via aspiration of the oil base. If possible, bring the labeling to the physician.

Reported HUMAN Effects from Exposure:
These symptoms have been reported in women and men following accidental exposure to altrenogest products, including OvaMed, either through handling of the product or contact with contaminated surfaces:

- Adverse reproductive effects reported in women included abnormal or absent menstrual cycles.
- Adverse reproductive effects reported in men included decreased libido.
- Other adverse events reported in women and men included headaches, fever, abdominal pain, nausea, diarrhea, vomiting, and rashes.

ANIMAL SAFETY WARNINGS AND PRECAUTIONS:
Keep OvaMed in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
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, especially masculinization of the female genitalia.

OTHER WARNINGS:
Do not use in horses intended for human consumption.

CONTACT INFORMATION:

- To report suspected adverse events, or to obtain product information, including Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332.
- For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www/fda.gov/reportanimalae

REPRODUCTIVE SAFETY STUDY:
A 3-year well-controlled reproductive safety study was conducted in 27 pregnant mares, and compared with 24 untreated control mares. Treated mares received 2 mL altrenogest solution 0.22%/110 lb body weight (2x dosage recommended for estrus suppression) from day 20 to day 325 of gestation. This study provided the following data:
1. In filly offspring (all ages) of treated mares, clitoral size was increased.

2. Filly offspring from treated mares had shorter interval from Feb. 1 to first ovulation than fillies from their untreated mare counterparts.
3. There were no significant differences in reproductive performance between treated and untreated animals (mares & their respective offspring) measuring the following parameters:

- interval from Feb. 1 to first ovulation, in mares only.
- mean interovulatory interval from first to second cycle and second to third cycle, mares only.
- follicle size, mares only.
- at 50 days gestation, pregnancy rate in treated mares was 81.8% (9/11) and untreated mares was 100% (4/4).
- after 3 cycles, 11/12 treated mares were pregnant (91.7%) and 4/4 untreated mares were pregnant (100%).
- colt offspring of treated and control mares reached puberty at approximately the same age (82 & 84 weeks, respectively).
- stallion offspring from treated and control mares showed no differences in seminal volume, spermatozoal concentration, spermatozoal motility, and total sperm per ejaculate.
- stallion offspring from treated and control mares showed no difference in sexual behavior.
- testicular characteristics (scrotal width, testis weight, parenchymal weight, epididymal weight and height, testicular height, width & length) were the same between stallion offspring of treated and control mares.

References:
Shoemaker, C.F., E.L. Squires, and R.K. Shideler. 1989. Safety of Altrenogest in Pregnant Mares and on Health and Development of Offspring. Eq. Vet. Sci. (9); No. 2: 69-72.
Squires, E.L., R.K. Shideler, and A.O. McKinnon. 1989: Reproductive Performance of Offspring from mares Administered Altrenogest During Gestation. Eq. Vet. Sci. (9); No. 2: 73-76.

HOW SUPPLIED:
OvaMed (altrenogest) contains 2.2 mg/mL altrenogest in an oil solution. Product is supplied in 1000 mL plastic bottles.

STORAGE, HANDLING, AND DISPOSAL:
Store OvaMed solution bottle at or below room temperature, 77°F (25°C). Close tightly. Place empty drug containers, protective gloves, or other articles that contain this product in a leak-resistant container for disposal in accordance with applicable Federal, state, and local regulations.

Approved by FDA under ANADA # 200-481
Restricted Drug (California) – use only as directed.
Manufactured for: Bimeda, Inc., Le Sueur, MN 56058, USA
N.A. Corp. Address: Bimeda, Inc., One Tower Lane, Oakbrook Terrace, IL 60181, USA
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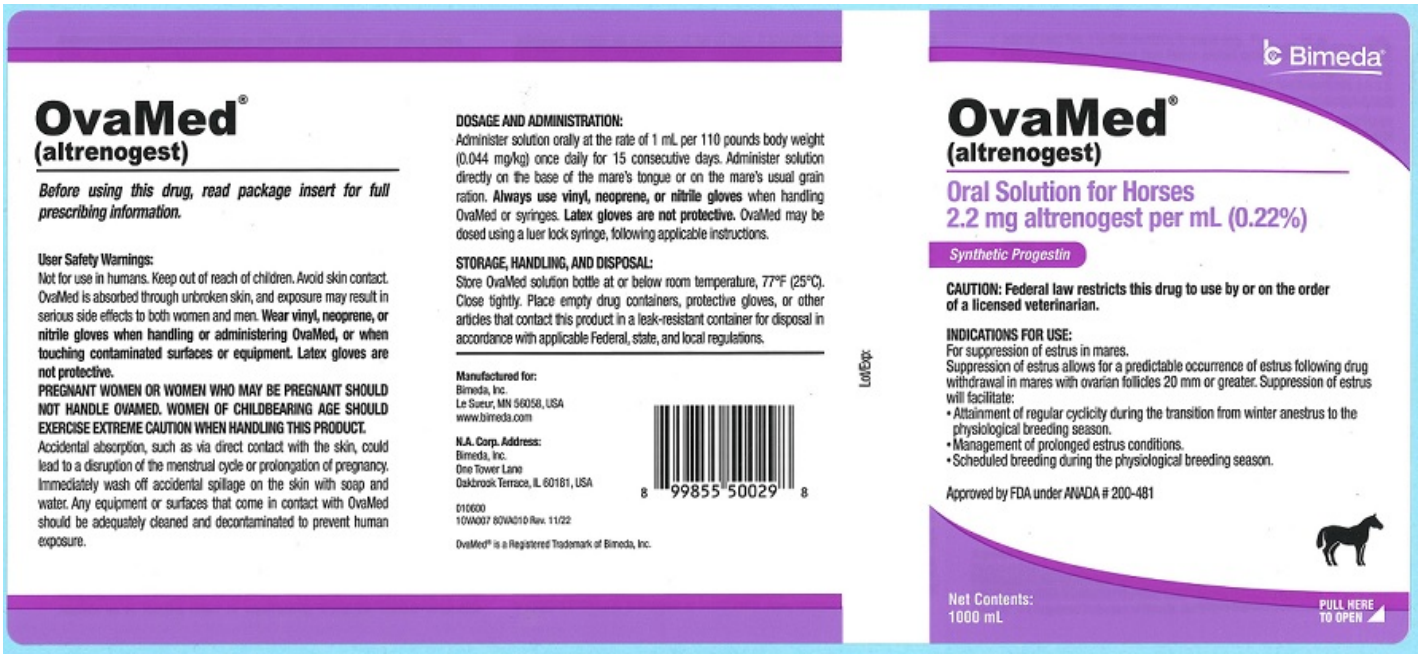

OVAMED

altrenogest solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:61133-8261
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:61133-8261-1	1000 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
ANADA	ANADA200481	01/03/2017	

Labeler - Bimeda, Inc. (060492923)

Revised: 5/2024 Bimeda, Inc.