SWINEMATE- altrenogest solution
Aurora Pharmaceutical, Inc.

SwineMate®
(altrenogest)

Oral Solution

2.2 mg altrenogest per mL (0.22%)

Synthetic progestin

FOR USE IN SWINE ONLY

USES:

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

It is a violation of Federal law to use this drug product other than as directed in the labeling or as directed by your veterinarian.

DESCRIPTION:

SwineMate® (altrenogest) Oral Solution contains 2.2 mg altrenogest per mL (0.22%) in an oil solution.

WARNINGS:

WITHDRAWAL PERIODS

Animals intended for human consumption must not be slaughtered within 21 days of the last treatment with this drug product.

USER SAFETY WARNINGS:

Not for use in humans. Keep out of the reach of children.

Skin contact must be avoided as SwineMate® is readily absorbed through unbroken skin, and exposure may result in serious side effects to both women and men. **Always wear vinyl, neoprene or nitrile protective gloves when handling SwineMate** or when in contact with equipment or surfaces contaminated by this product. **Latex gloves are not protective.**

PREGNANT WOMEN OR WOMEN WHO MAY BE PREGNANT SHOULD NOT HANDLE SwineMate® (altrenogest). WOMEN OF CHILDBEARING AGE SHOULD EXERCISE EXTREME CAUTION WHEN HANDLING THIS PRODUCT.

Accidental absorption, such as absorption through the skin, 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. Any equipment or surfaces that come in contact with SwineMate® should be adequately cleaned and decontaminated to prevent human exposure.

PEOPLE WHO SHOULD NOT HANDLE SwineMate®:*
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.

**Based on known effects of long-term progestin use in humans.*

ACCIDENTAL EXPOSURE:

SwineMate® is readily absorbed from contact with the skin. In addition, this oil-based product can penetrate latex or other types of porous gloves. **Always wear vinyl, neoprene, or nitrile protective gloves when handling SwineMate®. Latex gloves are not protective.** If SwineMate® gets inside gloves by damage or spilling, the covered skin may absorb more of the drug. Side effects after a single exposure are possible; however, continued daily exposure has the potential for more serious effects.

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. SwineMate® 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:

Side effects have been reported in women and men following accidental exposure to altrenogest products, including SwineMate®, either through handling of the product or contact with contaminated surfaces.
- Reproductive side effects reported in women included abnormal or absent menstual cycles.
- Reproductive side effects in men included decreased libido.
- Other side effects reported in women and men included headaches, fever, abdominal pain, nausea, diarrhea, vomiting, and rashes.

ANIMAL SAFETY WARNINGS:

Do not use SwineMate® in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis).

Underdosing of SwineMate® may lead to the occurance of cysitc follicles.

OTHER EFFECTS YOU MAY NOTICE:

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.

DIRECTIONS:

While wearing **vinyl, neoprene, or nitrile** gloves, remove shipping cap and seal; replace with enclosed plastic dispensing cap. This product can penetrate latex or other types of porous gloves. **Latex gloves are not protective.** 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 SwineMate® 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.

HOW SUPPLIED:

SwineMate® (altrenogest) Oral Solution contains 2.2 mg/mL (0.22%) of the active ingredient, packaged in 1,000 mL plastic bottles.

STORAGE, HANDLING, AND DISPOSAL:

Store SwineMate® solution bottle at or below room temperature, 77ºF (25ºC). Close tightly. Place empty drug containers, protective gloves, or other articles that contact this product in a leak-resistant container for disposal in accordance with applicable Federal, state, and local regulations.

QUESTIONS? COMMENTS?

- To report side effects, contact Aurora Pharmaceutical at 1-888-215-1256 or www.aurorapharmaceutical.com
- To obtain product information, including a safety data sheet (SDS), call 1-888-215-1256.
- For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or online at: www.fda.gov/reportanimalae

Approved by FDA under ANADA # 200-621

Restricted Drug (California) - use only as directed.

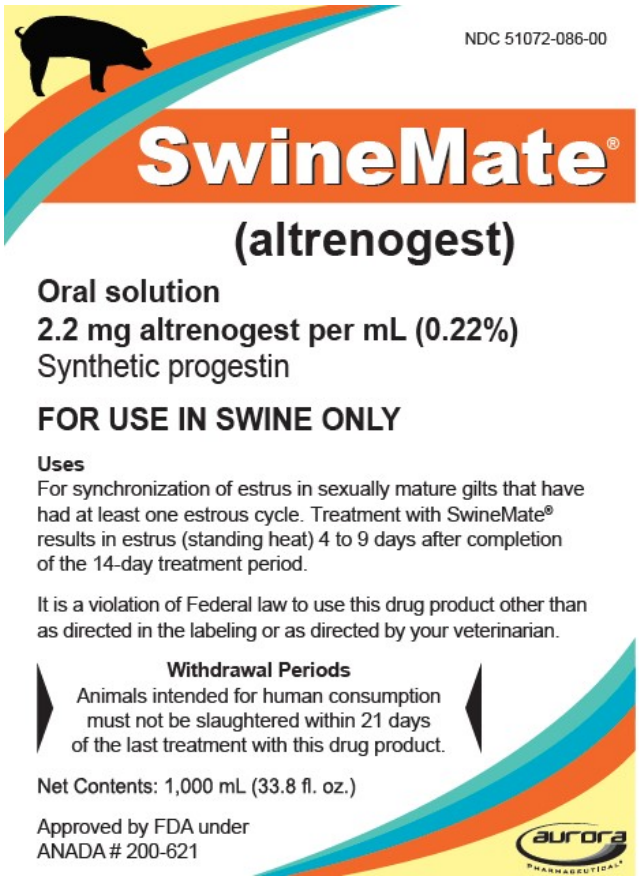
REORDER NO: 22000

Manufactured by:
Aurora Pharmaceutical, Inc.
NORTHFIELD, MN 55057
1-888-215-1256
www.aurorapharmaceutical.com
IN 50-1408 03/2024

NDC 51072-086-00

Container Label

PRINCIPAL DISPLAY PANEL - 1000 mL bottle label



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Approved by FDA under ANADA # 200-621

Restricted Drug (California) — use only as directed.

TAKE TIME OBSERVE LABEL DIRECTIONS

REORDER NO: 22000

MANUFACTURED BY:
Aurora Pharmaceutical, Inc.
NORTHFIELD, MINNESOTA 55057
www.aurorapharmaceutical.com

Manufactured in the USA
IN 50-1408 03/2024

Warning Shipper Label

IN 50-1464 03/2024

SwineMate®
(altrenogest)

Oral solution
2.2 mg altrenogest per mL (0.22%)

FOR USE IN SWINE ONLY

Before using this drug, read package insert for complete product information.

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WARNINGS

Withdrawal Periods
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Manufactured in the USA

Manufactured by:
Aurora Pharmaceutical, Inc.
NORTHFIELD, MINNESOTA 55057

Approved by FDA under ANADA # 200-621

Net Contents: 6 x 1,000 mL bottles

IN 50-1464 03/2024

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SWINEMATE
altrenogest solution

Product Information

Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:51072-086
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 (colorless to yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-086-00	1000 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200621	08/02/2017	

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment

Name	Address	ID/FEI	Business Operations
Aurora Pharmaceutical, Inc.		832848639	manufacture

Revised: 6/2024 Aurora Pharmaceutical, Inc.