OVUGEL- triptorelin acetate gel
Aurora Pharmaceutical, Inc.

OvuGel

ACTIVE INGREDIENT:

triptorelin acetate

DOSAGE FORM & STRENGTH:

100 mcg triptorelin per mL (as triptorelin acetate)
Gel for intravaginal use

INDICATIONS FOR USE:

For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination. Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals.

DESCRIPTION:

OvuGel is a thin, clear to slightly hazy gel. Each mL of OvuGel contains 100 mcg of triptorelin (as triptorelin acetate) for intravaginal administration.

WARNINGS:

WITHDRAWAL PERIOD:
No withdrawal period is required when used according to labeling.

USER SAFETY WARNINGS:
Not for Use in Humans. Keep Out of Reach of Children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information.

ANIMAL SAFETY WARNINGS:
OvuGel should not be used in sows with obvious reproductive tract abnormalities.

RECOMMENDATIONS FOR SAFE AND EFFECTIVE USE:

Use of a bottle mount multi-dose applicator is recommended to ensure accurate dosing. The use of adequate sperm numbers per insemination and proper semen storage, as recommended by the semen or artificial inseminator catheter suppliers, is recommended.

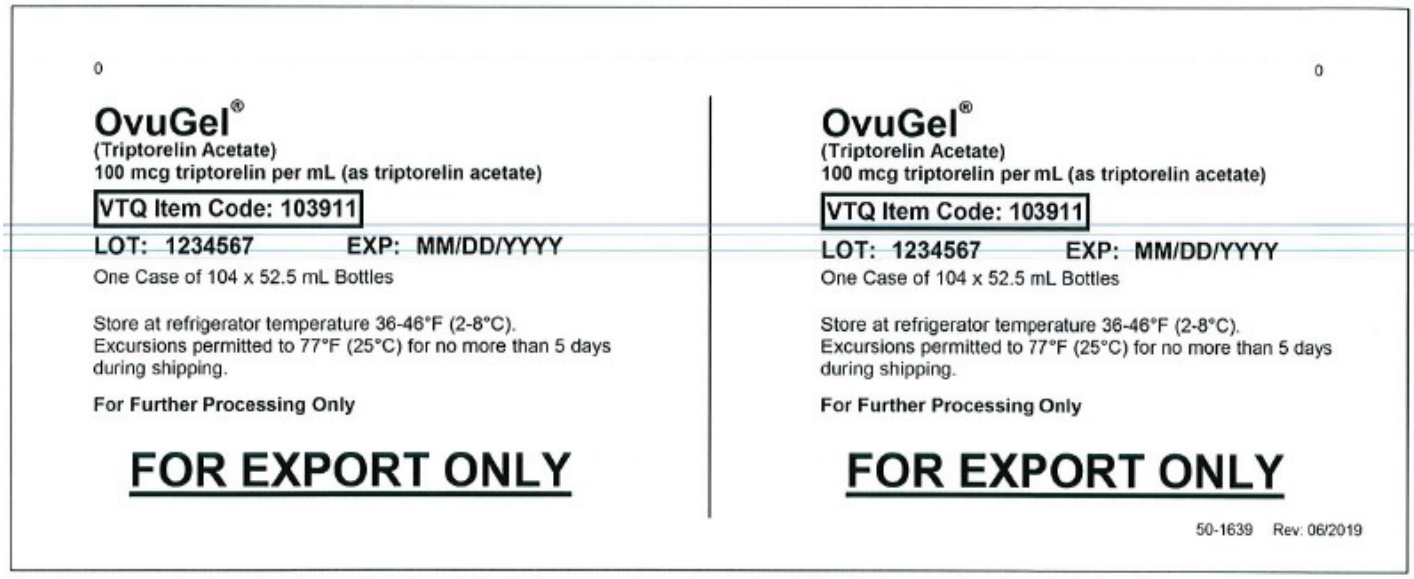
DIRECTIONS FOR USE:

OvuGel should be administered intravaginally at approximately 96 hours after weaning. The product should be warmed at room temperature for a minimum of 10 minutes prior to use. Insert the delivery tube into the vagina so that the tip rests 1/2 inch (1-3 cm) posterior to the cervix. Use a separate sheath over the delivery tube for each sow treated. Each sow should receive a single 2 mL dose of OvuGel. Sows should be inseminated 22 +/- 2 hours following administration of OvuGel using standard artificial insemination techniques. Sows should be exposed to a boar during time of insemination. (See end of package insert for more detailed directions for OvuGel administration).

STORAGE, HANDLING, AND DISPOSAL:

Store at refrigerator temperature 36-46°F (2-8°C). Excursions permitted to 77°F (25°C) for no more than 5 days during shipping.
OvuGel should be administered within 1 hour of warming; unused portions may be refrigerated immediately after use. The bottle stopper may be punctured a maximum of three times. Discard 28 days after the stopper is first punctured.

Shipper label - case of 52.5 mL bottles



OVUGEL

triptorelin acetate gel

Product Information			
Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:51072-087
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Triptorelin Acetate (UNII: 43OFW291R9) (Triptorelin - UNII:9081Y98W2V)	Triptorelin	100 ug in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-087-01	52.5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		06/09/2023	

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment

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

Revised: 6/2023 Aurora Pharmaceutical, Inc.