

SYNOVEX PRIMER- trenbolone acetate and estradiol benzoate implant
Zoetis Inc.

SYNOVEX Primer®

SYNOVEX Primer®
(trenbolone acetate and estradiol benzoate implants)
50 mg trenbolone acetate and 7 mg of estradiol benzoate per implant

SUBCUTANEOUS IMPLANTS FOR GROWING BEEF STEERS AND HEIFERS ON PASTURE
AND IN A DRY LOT

SYNOVEX® PRIMER™ (trenbolone acetate and estradiol benzoate implants) is a growth promoting implant containing 50 mg of trenbolone acetate and 7 mg of estradiol benzoate per implant. Each implant consists of 2 pellets. Ten implants are provided in each cartridge.

WITHDRAWAL PERIODS AND RESIDUE WARNINGS

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

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

ANIMAL SAFETY WARNINGS

Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered **SYNOVEX® PRIMER™** implants.

DIRECTIONS

Administer one **SYNOVEX® PRIMER™** implant (two pellets), containing 50 mg of trenbolone acetate and 7 mg of estradiol benzoate, to each steer or heifer by subcutaneous implantation in the middle-third of the ear.

Use only a SYNOVEX applicator. Approved implantation technique is fully described in the fold-out carton section. Never sacrifice careful, clean technique for speed of implantation.

STORAGE

Store unopened product at controlled room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F). Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions 2°-8°C (36°-47°F) or at room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F) for up to one month.

DISPOSAL

SYNOVEX® PRIMER™ waste materials should be disposed of according to prescribed Federal, State, and Local guidelines.

INDICATIONS FOR USE

- For increased rate of weight gain in growing beef steers and heifers on pasture (stocker, feeder, and slaughter).
- For increased rate of weight gain in growing beef steers and heifers in a dry lot.¹
- This implant is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture or in a dry lot as safety and effectiveness have not been evaluated.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.

Do not use in animals intended for subsequent breeding, or in dairy cows.

¹CVM Appendix III of GFI 191, August 27, 2020, <https://www.fda.gov/animal-veterinary/new-animal-drugapplications/classes-major-food-producing-animals-newanimal-drug-applications#beef>

QUESTIONS/COMMENTS?

For a copy of the Safety Data Sheet or to report side effects, contact Zoetis Inc. at 1-888-963-8471. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Manufactured By A Non-Sterilizing Process

Restricted Drug (California)—Use Only As Directed.

IMPORTANT

Read ALL sides of carton

Approved by FDA under NADA # 141-043

NET CONTENTS: 10 CARTRIDGES

Each Cartridge Contains 10 implants (100 implants total)

zoetis

Distributed by:

Zoetis Inc.

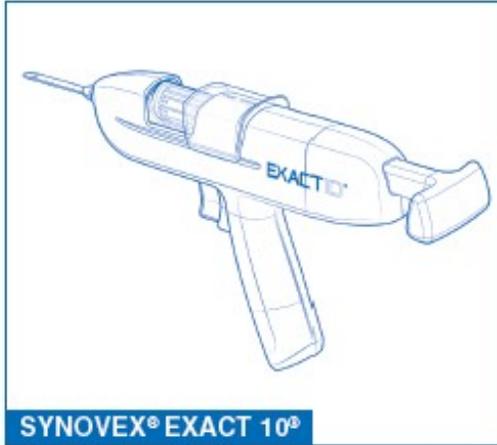
Kalamazoo, MI 49007

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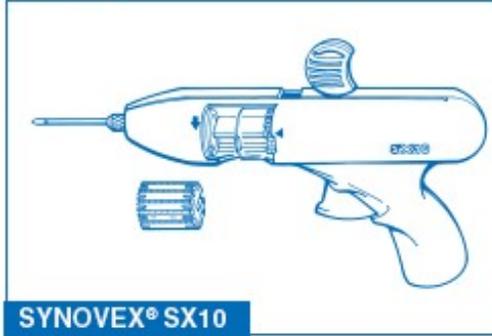
PRINCIPAL DISPLAY PANEL - 10 Cartridge Implant Carton

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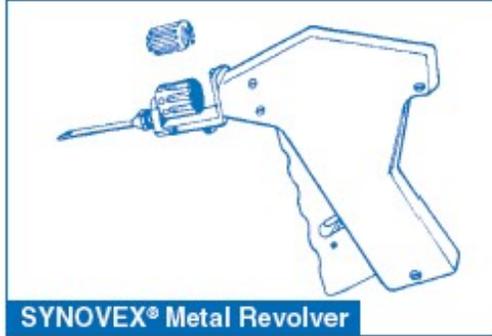
SYNOVEX® Applicators



SYNOVEX® EXACT 10®



SYNOVEX® SX10



SYNOVEX® Metal Revolver

SYNOVEX® PRIMER™

(trenbolone acetate and estradiol benzoate implants)
50 mg trenbolone acetate and 7 mg of estradiol benzoate per implant

HOW TO IMPLANT For use with a SYNOVEX Applicator

Study the following instructions carefully, then proceed step by step, until the technique becomes routine. Many head can be implanted per hour by an experienced team, one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used.

Restricted Drug (California)—
Use Only as Directed.
Revised: October 2024

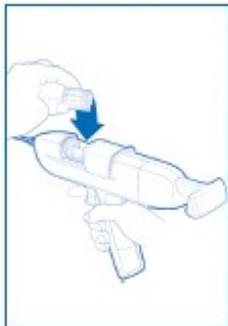
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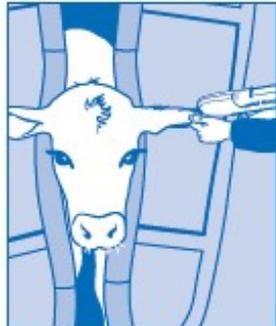
STEP 1 Loading The Applicator



Load the applicator following the directions outlined in the instruction manual accompanying each applicator.

Additional information and individual applicator user guides can be found at: www.synovex.com or scan the QR code.

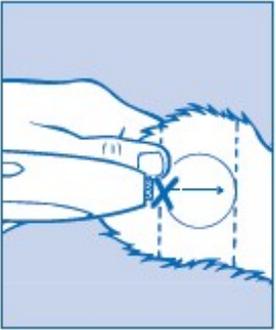
STEP 2 Restraint



The animal must be confined in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a firm bristled brush that has been soaked in a germicidal solution.

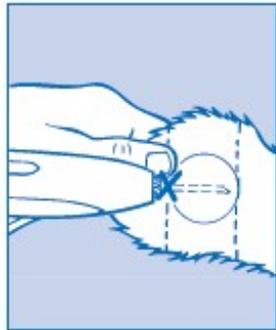
Note: If implanting horned cattle, greater safety is provided with secure head control. Use a halter or nose tongs if necessary.

STEP 3 Implant Site



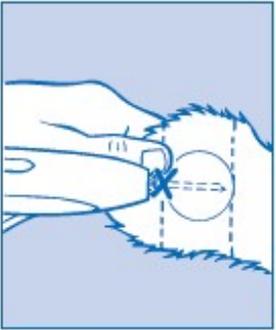
Divide the ear into three imaginary sections as illustrated. The implanted pellets should be deposited in the center one-third of the ear as shown. To accomplish this, the applicator needle should be inserted in the outer one-third of the ear as indicated by the "X" in the illustration. Implanting too close to the head may cause abnormal sexual behavior. Care should be taken to avoid severing the major arteries of the ear.

STEP 4 Insert Needle



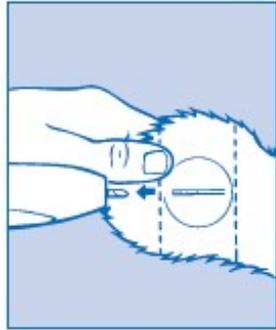
Grasp the ear with one hand. Holding the applicator firmly with the other hand, penetrate the skin at the point shown by the "X". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the applicator forward (toward the base of the ear) until the full needle length is beneath the skin.

STEP 5 Pellet Implantation



When the needle is completely inserted, activate the instrument by squeezing the trigger completely. Refer to instructions for individual applicator.

STEP 6 Inspection



Check the implant site. If properly administered, the implants should lie in a straight line under the skin.

Re-cock the applicator. Disinfect the applicator needle in a germicidal solution. The applicator is now ready to implant the next animal.



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SYNOVEX PRIMER			
trenbolone acetate and estradiol benzoate implant			
Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-6870
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRENBOLONE ACETATE (UNII: RUD5Y4SV0S) (TRENBOLONE - UNII:P53R4420TR)	TRENBOLONE ACETATE	50 mg
ESTRADIOL BENZOATE (UNII: 1S4CJB5ZGN) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL BENZOATE	7 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-6870-1	1 in 1 BOX		
1		10 in 1 POUCH		
1		10 in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141043	07/01/2024	

Labeler - Zoetis Inc. (828851555)

Revised: 2/2025

Zoetis Inc.