

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

SYNOVEX® ONE FEEDLOT

SYNOVEX® ONE FEEDLOT
(trenbolone acetate and estradiol benzoate extended-release implants)
200 mg trenbolone acetate and 28 mg estradiol benzoate per implant

**SUBCUTANEOUS IMPLANTS FOR STEERS AND HEIFERS FED IN CONFINEMENT
FOR SLAUGHTER**

SYNOVEX® ONE Feedlot (trenbolone acetate and estradiol benzoate extended-release implants) is a growth promoting implant containing 200 mg of trenbolone acetate and 28 mg of estradiol benzoate per implant with a porous polymer film coating that extends the pay-out period of the final formulation up to 200 days. Each implant consists of 8 pellets. Ten implants are provided in each cartridge.

NOTE: Administration of a single SYNOVEX® ONE Feedlot implant or its use in a reimplantation program with a SYNOVEX Choice® implant may result in decreased marbling scores when compared to non-implanted steers and heifers.

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 WARNING

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® ONE Feedlot implants.

DIRECTIONS

Administer one SYNOVEX® ONE Feedlot implant (eight pellets), containing 200 mg trenbolone acetate and 28 mg estradiol benzoate, to each steer or heifer by

subcutaneous implantation in the middle-third of the ear. If using in a reimplantation program, reimplant steers or heifers with a SYNOVEX® ONE Feedlot implant 60 to 120 days after administering a SYNOVEX Choice® implant.

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® ONE Feedlot waste materials should be disposed of according to prescribed Federal, State, and Local guidelines.

INDICATIONS FOR USE

- For increased rate of weight gain and improved feed efficiency for up to 200 days in growing beef steers and heifers fed in confinement for slaughter.
- For increased rate of weight gain for up to 200 days in growing beef steers and heifers fed in confinement for slaughter in a reimplantation program where SYNOVEX Choice® is the first implant and a SYNOVEX® ONE Feedlot implant is administered 60 to 120 days later.
- Other than as described on the labeling, this implant is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter 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.

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>.

SYNOVEX Choice® (trenbolone acetate and estradiol benzoate implants) is owned by Zoetis.

Manufactured By A Non-Sterilizing Process

Restricted Drug (California)—Use Only As Directed.

IMPORTANT

Read ALL sides of carton

Approved by FDA under NADA # 141-348

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revision Date: April 2022

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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

SYNOVEXONE
FIBRINOLYSE

Prothrombin activator and activator (enzyme) (human placenta extract)
100 mg (100,000 units) and 10 mg (10,000 units) per Syringe

HOW TO IMPLANT For use with the SYNOVEX Applicator

Study the following instructions carefully, then proceed step by step, until the technique becomes routine. Many heads 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.

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STEP 1 Loading The Applicator



Load the applicator following the directions outlined in the instruction manual accompanying each applicator. When using metal revolver style applicator, use orange adapter kit.

Additional information for the individual applicator user guides can be found at: www.pcrwithanovex.com.

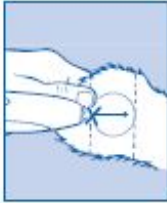
STEP 2 Restraint



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.

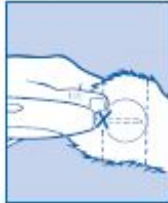
Note: If implanting horned cattle, greater safety is provided when the head is controlled by the use of a bull lead (nose tong).

STEP 3 Implant Site



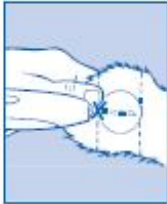
Divide the ear into three imaginary sections as illustrated. The implanted pellets should be deposited in the center one-third of the ear as shown. To accomplish this, the applicator needle should be inserted in the outer one-third of the ear as indicated by the "X" in the illustration. Implanting too 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 being 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. Cleanse the applicator needle in a germicidal solution. The applicator is now ready to implant the next animal.



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(trenbolone acetate and estradiol benzoate extended-release implants)

200 mg trenbolone acetate and 28 mg estradiol benzoate per implant

SYNOVEX ONE

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Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-2010
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
trenbolone acetate (UNII: RUD5Y4SV0S) (trenbolone - UNII:P53R4420TR)		trenbolone acetate	200 mg
estradiol benzoate (UNII: 1S4CJB5ZGN) (estradiol - UNII:4TI98Z838E)		estradiol benzoate	28 mg

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-2010-1	10 in 1 CARTON		
1		10 in 1 CARTRIDGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141348	06/10/2014	

Labeler - Zoetis Inc. (828851555)

Revised: 8/2022

Zoetis Inc.