

SYNOVEX H- testosterone propionate and estradiol benzoate implant
Zoetis Inc.

Synovex H

Synovex® H

(testosterone propionate and estradiol benzoate implants)

200 mg testosterone propionate and 20 mg estradiol benzoate per implant

SUBCUTANEOUS IMPLANTS FOR GROWING BEEF HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

This product was manufactured by a non-sterilizing process.

TAKE TIME OBSERVE LABEL DIRECTIONS

Important: Read ALL sides of carton

For subcutaneous ear implantation only.

Approved by FDA under NADA # 011-427

NET CONTENTS: 10 CARTRIDGES

Each Cartridge Contains 10 implants (100 implants total)

Restricted Drug (California) — Use Only as Directed

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® H implants.

INDICATIONS FOR USE

- For increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter.
- 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 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 evaluated.

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

Dosage

Implant complete contents of one cartridge cell per heifer. Approved implantation technique is fully described in the package insert.

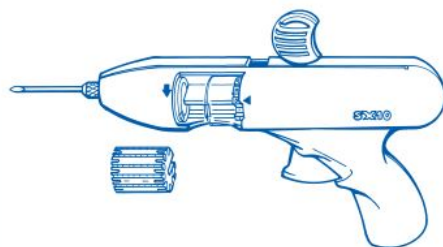
NOTE: Never sacrifice careful, clean technique for speed of implantation.

<p>HOW TO IMPLANT WITH SYNOVEX® H (testosterone propionate and estradiol benzoate implants) 200 mg testosterone propionate and 20 mg estradiol benzoate per implant</p> <hr/> <p>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. This person should maintain hand cleanliness and use sanitary instruments only.</p> <p>HOW SUPPLIED</p> <p>100 Dose</p>	<p>SYNOVEX® H Implants (testosterone propionate and estradiol benzoate implants) 200 mg testosterone propionate and 20 mg estradiol benzoate per implant</p> <p>INDICATIONS FOR USE:</p> <ul style="list-style-type: none">· For increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter.· 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 heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. <p>Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated.</p> <p>Do not use in animals intended for subsequent breeding, or in dairy cows.</p> <p>Store at controlled room temperature 20° to 25°C (68° to 77°F) with excursions between 15°-30°C (59°-86°F). Avoid excessive heat or humidity.</p>	<p>SYNOVEX® H Implants (testosterone propionate and estradiol benzoate implants) 200 mg testosterone propionate and 20 mg estradiol benzoate per implant</p> <p>WITHDRAWAL PERIODS AND RESIDUE WARNINGS:</p> <p>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.</p> <p>USER SAFETY WARNINGS: Not for use in humans. Keep out of reach of children.</p> <p>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® H implants.</p> <p>Restricted Drug (California)— Use Only as Directed</p>
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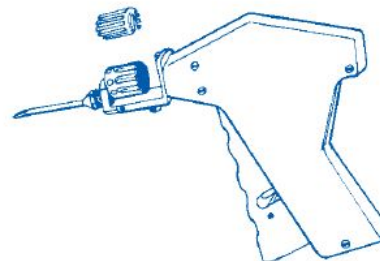
SYNOVEX® EXACT 10® Applicator



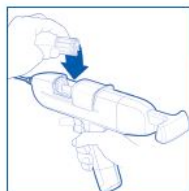
SYNOVEX® SX10 Applicator



SYNOVEX® Metal Revolver



STEP 1 Loading the Applicator



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

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

STEP 2 Restraint

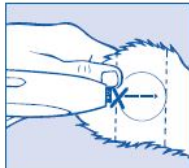


The animal must be confined in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a firm bristled brush that has been soaked in a germicidal solution.

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

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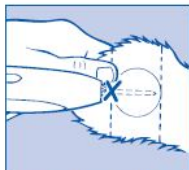
STEP 3 Implant Site



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

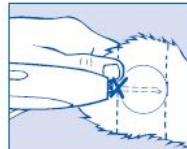


Grasp the ear with one hand. While holding the applicator firmly with the other hand, penetrate the skin at the point shown by the "X". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the applicator

forward (toward the base of the ear) until the full needle length is beneath the skin.

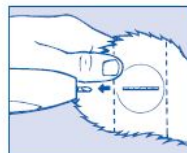
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STEP 5 Pellet Implantation



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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Kalamazoo, MI 49007

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DIRECTIONS

Implant complete contents of one cartridge cell per heifer. Approved implantation technique is fully described in the package insert.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

Storage

Store at controlled room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F). Avoid excessive heat or humidity.

HOW SUPPLIED

100 Dose

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>.

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Kalamazoo, MI 49007


Revised: May 2023
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PRINCIPAL DISPLAY PANEL - Carton of 10 cartridges

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Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-3901
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TESTOSTERONE PROPIONATE (UNII: W93Z9138A) (TESTOSTERONE - UNII:3XMK78S47O)	TESTOSTERONE PROPIONATE	200 mg
ESTRADIOL BENZOATE (UNII: 1S4CJB5ZGN) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL BENZOATE	20 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-3901-1	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	NADA011427	11/07/2014	

Labeler - Zoetis Inc. (828851555)

Revised: 7/2023

Zoetis Inc.