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COMPONENT™ TE-IH WITH TYLAN™

Elanco US

(trenbolone and estradiol and tylosin implant)

Each implant consists of 80 mg trenbolone acetate, 8 mg estradiol USP and 29 mg tylosin tartrate

FOR GROWING BEEF HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

20-dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-IH with Tylan (trenbolone and estradiol and tylosin implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. Component TE-IH (trenbolone and estradiol implant) Implants are recommended for use in heifers fed in confinement for slaughter for INCREASED RATE OF WEIGHT GAIN.

INDICATIONS FOR USE: This product contains trenbolone acetate and estradiol for increased rate of weight gain in a slow-release delivery system. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following reimplantation have not been evaluated.

NOTE: Studies have demonstrated that administration of Component TE-IH can result in decreased marbling scores when compared to non-implanted heifers.

DOSAGE: Administer 1 implant per animal according to the following instructions.

GENERAL INSTRUCTIONS: Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

WARNING: Not to be used in animals intended for subsequent breeding, or in dairy

animals. Implant one dose - 5 pellets (entire contents of one cartridge cell) - in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

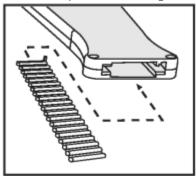
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

RESTRICTED DRUG (CALIFORNIA) - USE ONLY AS DIRECTED - NOT FOR HUMAN USE - KEEP OUT OF REACH OF CHILDREN

IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.



Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets

After inserting the needle fully in the correct position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

Storage Conditions

Store unopened product at or below 25°C (77°F).

Avoid excessive heat and humidity.

Use before the expiration date printed on foil pouch.

Discard open foil pouches.

Approved by FDA under ANADA 200-346,

Manufactured by a non-sterilizing process.

Component TE-IH with Tylan (trenbolone and estradiol and tylosin implant) is covered by U.S. Patent No. 5,874,098

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Tylosin: Product of the United Kingdom

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data sheet (SDS), contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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