

**COMPONENT TE-H WITH TYLAN- trenbolone acetate, estradiol, tylosin tartrate implant  
Elanco US Inc.**

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***TE-H with Tylan***  
**(trenbolone and estradiol and tylosin implant)**

***Elanco™***

***Component™***

***HEIFERS***

**(trenbolone and estradiol and tylosin implant)**

Each implant consists of 140 mg trenbolone acetate,

14 mg estradiol USP and 29 mg tylosin tartrate

**FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER**

20 dose Cartridge Belt

**Use with a Component Implanter**

**For Use In Animals Only**

**DESCRIPTION:**

Each cartridge belt holds 20 doses of Component TE-H with Tylan (trenbolone and estradiol and tylosin implant) Implants. Each dose of 8 pellets consists of 7 pellets containing a total of 140 mg of trenbolone acetate and 14 mg estradiol USP plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. Component TE-H (trenbolone and estradiol implant) Implants are recommended for use in heifers fed in confinement for slaughter for **INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.**

**INDICATIONS FOR USE:**

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

**DOSAGE:**

Administer 1 implant per animal according to the following instructions.

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

**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 — 8 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.

**A withdrawal period has not been established for this product in pre-ruminating calves.**

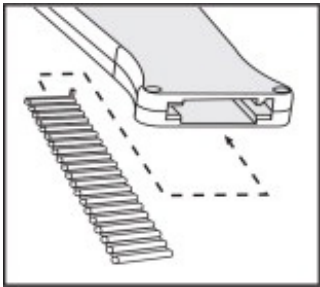
**Do not use in calves to be processed for veal.**

**RESTRICTED DRUG (CALIFORNIA) — USE ONLY AS DIRECTED — FOR USE IN ANIMALS ONLY — 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 implant position, squeeze the trigger fully. 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 in a refrigerator 2° to 8°C (36° to 46°F) and protect from sunlight.

Use before the expiration date printed on foil pouch. Discard open foil pouches.

ANADA 200-346, Approved by FDA

### **Manufactured by a non-sterilizing process.**

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

Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

Distributed by Elanco US Inc., Greenfield, IN 46140, USA

Tylosin: Product of the United Kingdom

To report adverse events, access medical information, or to obtain additional product information, call 1-800-428-4441

PA100980X

AH0342

### **Principal Display Panel – Carton Label**

**Elanco™**  
**Component™**  
**TE-H with Tylan™**  
**(trenbolone and estradiol and tylosin implant)**  
**HEIFERS**

**Storage Conditions**

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**Elanco™**  
**Component™** **TE-H with Tylan™**  
**(trenbolone and estradiol and tylosin implant)**  
**HEIFERS**

Each implant consists of 140 mg trenbolone acetate, 14 mg estradiol USP and 29 mg tylosin tartrate  
**FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER**

**Indications:** Component TE-H with Tylan (trenbolone and estradiol and tylosin implant) contains trenbolone acetate and estradiol for increased rate of weight gain and improved feed efficiency in a slow-release delivery system. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**Contents:** 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 140 mg and estradiol USP 14 mg with 29 mg tylosin tartrate as a local antibacterial.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions.

ANADA 200-346, Approved by FDA

**100 IMPLANTS**

TAKE TIME  
 OBSERVE LABEL DIRECTIONS



Use with a Component Implant

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 Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

▶ **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 —**  
**FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Note:** Studies have demonstrated that the administration of Component TE-H (trenbolone and estradiol implant) can result in decreased marbling scores when compared to non-implanted heifers.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

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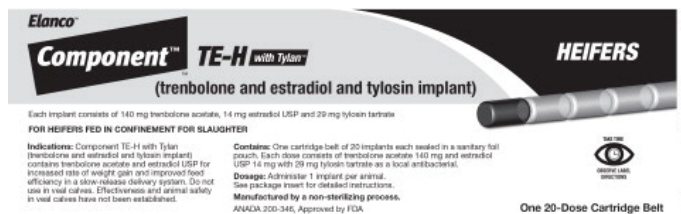
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**(trenbolone and estradiol and tylosin implant)**  
**Component™ TE-H with Tylan™**  
**Elanco**

AH0342

**Principal Display Panel – Pouch Label**

**Elanco™**  
**Component™**  
**TE-H with Tylan™**  
**(trenbolone and estradiol and tylosin implant)**  
**HEIFERS**



**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 8 pellets (in the contacts of one cartridge call) — 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.

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# COMPONENT TE-H WITH TYLAN

trenbolone acetate, estradiol, tylosin tartrate implant

## Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:58 198-0342
<b>Route of Administration</b>	SUBCUTANEOUS		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trenbolone acetate (UNII: RUD5Y4SV0S) (trenbolone - UNII:P53R4420 TR)	trenbolone acetate	140 mg
estradiol (UNII: 4TI98 Z8 38 E) (estradiol - UNII:4TI98 Z8 38 E)	estradiol	14 mg
tylosin tartrate (UNII: 5P4625C51T) (tylo sin - UNII:YEF4JXN031)	tylo sin tartrate	29 mg

## Inactive Ingredients

Ingredient Name	Strength
CHOLESTEROL (UNII: 97C5T2UQ7J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
ETHYLCELLULOSES (UNII: 7Z8S9 VYZ4B)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 198-0342-1	5 in 1 CARTON		
1		1 in 1 POUCH		
1		20 in 1 CARTRIDGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200346	12/09/2013	

## Establishment

Name	Address	ID/FEI	Business Operations
Ivy Animal Health, Inc.		088106096	MANUFACTURE, PACK, LABEL

## Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia and Upjohn Company LLC		618054084	API MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Gedeon Richter Plc.		644781932	API MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Bayer AG		314398484	API MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Elanco Speke Operations		230761368	API MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Ivy Animal Health, Inc.		080698078	MANUFACTURE