

FREEDOM OF INFORMATION SUMMARY  
FOR  
COMPONENT® TE-G (TRENBOLONE ACETATE AND ESTRADIOL)

SEP 18 2000

1. GENERAL INFORMATION:

ANADA Number: 200-221

Sponsor: Ivy Animal Health, Inc.  
8857 Bond Street  
Overland Park, KS 66214

Generic Name: Trenbolone Acetate, Estradiol and Tylosin Tartrate

Trade Name: Component® TE-G with Tylan®

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: This supplement provides for the addition of a tylosin tartrate pellet as a local antibacterial to Component® TE-G.

2. INDICATIONS FOR USE:

Component® TE-G with Tylan®: For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).

3. DOSAGE FORM(S), ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

Dosage Form: Implantation

Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.

Recommended Dosage: Component® TE-G with Tylan®: One implant containing 40 mg trenbolone acetate and 8 mg estradiol (2 pellets), and 29 mg tylosin tartrate (1 pellet).

4. EFFECTIVENESS

The effectiveness requirement for this supplemental new animal drug application, with the indications for use and dosage as given in Sections 2 and 3 above, is met by utilizing the information contained in ANADA 200-221 and conducting the additional adequate and well-controlled study included in this supplemental application.

### **Pivotal Study:**

A study was conducted by William Barton, CAVL, Inc., Amarillo, TX, to evaluate the effectiveness of Component® TE-S with Tylan® (120 mg trenbolone acetate and 24 mg estradiol (6 pellets) and 29 mg tylosin tartrate (1 pellet)) to lower the incidence of ear abscess formation. This study was determined to be an appropriate model for Component TE-G, since Component TE-G (2 pellets) is an identical formulation but only 1/3 the dose of Component TE-S (6 pellets). An implant site abscess induction model was developed to reliably create a high abscess rate in test animals. This model was used to test the ability of a tylosin tartrate pellet to reduce implant site abscess incidence in animals expected to develop an ear abscess. In the study, 40 beef steers were subjected to the abscess-inducing culture at the same time they were implanted with either Component® TE-S with a Tylan® pellet or Component® TE-S alone. Implant sites were observed at regular intervals up to 35 days following implantation. Abscess rate at each time point was significantly lower ( $P < 0.0001$ ) in animals treated with Component® TE-S with a Tylan® pellet compared to animals treated with Component® TE-S alone, with the maximum incidence of abscesses of 5% and 100%, respectively.

### **5. TARGET ANIMAL SAFETY**

Target animal safety of Component® TE-G is established by data in the parent application. The data provided in the effectiveness study described above was sufficient to conclude that the use of the tylosin tartrate pellet was safe for use in cattle. No further studies were required.

### **6. HUMAN SAFETY**

Human safety is established for Component® TE-G by data in the parent application. No further studies were required for use of the tylosin tartrate pellet.

### **7. AGENCY CONCLUSIONS**

Adequate data demonstrates the safe and effective use of a tylosin tartrate pellet added to Component® TE-G as a local antibacterial.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change providing for the addition of a tylosin tartrate pellet as a local antibacterial to Component® TE-G. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

### **8. LABELING**

Facsimile labeling is attached as follows:

1. Component® TE-G with Tylan® Box Label
2. Component® TE-G with Tylan® 20 Dose Foil Pouch
3. Component® TE-G with Tylan® Package Insert

**RESTRICTED DRUG – USE ONLY AS DIRECTED (CALIFORNIA) – FOR USE IN ANIMALS ONLY  
NOT FOR HUMAN USE – KEEP OUT OF REACH OF CHILDREN**

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

# COMPONENT<sup>®</sup> TE-G

BRAND IMPLANTS

**FOR PASTURE CATTLE**  
(slaughter, stocker and feeder steers and helpers)



trenbolone acetate USP 40 mg and  
estradiol USP 8 mg with 29 mg tylosin tartrate as a local antibacterial



COMPONENT<sup>®</sup> TE-G contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and helpers).  
**Contains:** 5 Cartridge Belts\* of 20 implants each. Each dose consists of trenbolone acetate 40 mg and estradiol 8 mg with 29 mg tylosin tartrate as a local antibacterial.  
**Manufactured by a non-sterilizing process.**  
\* Patented by Ivy Animal Health, Inc., ANADA 200-221, Approved by FDA

100 IMPLANTS

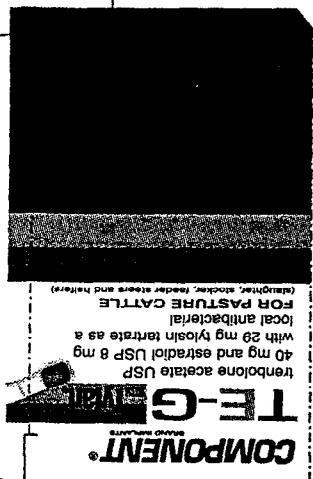


**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose – 3 pellets (entire contents of one cartridge) – in the ear subcutaneously. Any other site is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food

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

COMPONENT TE-G with Tylan is covered by U.S. Patent No. 5,874,098.  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 28 03 00



20 Dose Foil Pouch  
FRONT

ART

# COMPONENT<sup>®</sup> T-G

BRAND IMPLANTS

FOR PASTURE CATTLE

(slaughter, stocker, and feeder steers and heifers)

trenbolone acetate USP 40 mg and estradiol USP 8 mg with 29 mg tylosin tartrate as a local antibacterial



TEAR HERE

COMPONENT<sup>®</sup> TE-G contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).

**Contains:** One Cartridge Belts\* of 20 implants sealed in a sanitary foil pouch.

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

\* Patented by Ivy Animal Health, Inc., ANADA 200-221, Approved by FDA



One 20-Dose Cartridge Belt

1999150 Plus 200 2001 17 Plus 485 BLACK

OK as submitted

Signature \_\_\_\_\_

Flexo Job#- 1999150  
P.O #- 99-2114  
Part#- N/A  
Revision#- 0  
Date- 12/22/99  
Oper.- jg  
Attention- Tonya

# PROVAL FORM

TEAR HERE

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose – 3 pellets (entire contents of one cartridge) – 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.

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

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight. Use before the expiration date.

**Restricted Drug – Use Only As Directed (California) – For Use in Animals Only  
Not for Human Use – Keep Out of Reach of Children**

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Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
01 28 02 00

PURCHASE SEAL 20 IMPLANTS



EXP

LOT

3.125"

20 Dose Foil Pouch  
BACK

Correct and Reproof

Date \_\_\_\_\_

**COMPONENT<sup>®</sup>**  
GRAND IMPLANTS

**TE-G<sup>®</sup> WITH Tylan<sup>®</sup>**

**VetLife**

**FOR PASTURE CATTLE**  
(slaughter, stocker, feeder steers and heifers)

trenbolone acetate USP 40 mg  
and estradiol USP 8 mg with  
29 mg tylosin tartrate as a local antibacterial



**20 dose CARTRIDGE BELT\***

For use with the COMPONENT One Gun<sup>™</sup>  
For Use in Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT<sup>®</sup> TE-G Implants. Each dose of 3 pellets consists of 2 pellets containing a total of 40 mg of trenbolone acetate and 8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT TE-G Implants are recommended for use in pasture cattle (slaughter, stocker, feeder steers and heifers) for INCREASED RATE OF WEIGHT GAIN.

Manufactured by a non-sterilizing process.

**INDICATIONS FOR USE:** This product contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and 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**

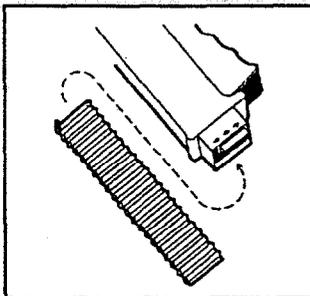
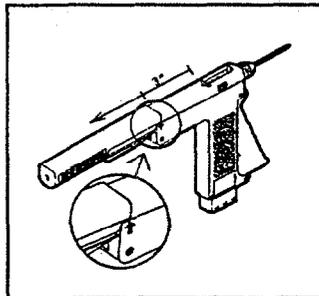
Not to be used in animals intended for subsequent breeding, or in dairy animals. For animal treatment only. Not for use in humans. Implant pellets in ear only. Any other location is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

KEEP THIS AND ALL OTHER DRUGS  
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 into animal's eyes.

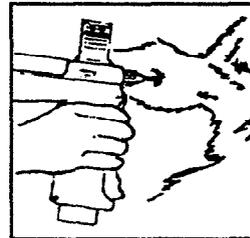
**Where to Implant**

The full contents of the cartridge 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. As the needle is withdrawn from the ear, the controlled-pressure plunger action 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 the 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°-8°C; 36°-46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 and 5,522,797 - Ivy Animal Health, Inc.

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