

JUL 20 1999

FREEDOM OF INFORMATION SUMMARY  
FOR  
COMPONENT® T-S & COMPONENT® T-H (Trenbolone Acetate)

1. GENERAL INFORMATION

NADA Number: 200-224

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

Generic Name: Trenbolone Acetate and Tylosin Tartrate

Trade Name: Component® T-S with Tylan®; Component® T-H 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® T-S and Component® T-H.

2. INDICATIONS FOR USE

*Component® T-S with Tylan®*: For improved feed efficiency in growing-finishing feedlot steers. *Component® T-H with Tylan®*: For increased rate of weight gain and improved feed efficiency in growing-finishing feedlot 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® T-S with Tylan®*: One implant containing 140 mg trenbolone acetate and 29 mg tylosin tartrate. *Component® T-H with Tylan®*: One implant containing 200 mg trenbolone acetate and 29 mg tylosin tartrate.

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 200-224 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<sup>®</sup> T-S with Tylan<sup>®</sup> to lower the incidence of ear abscess formation. 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<sup>®</sup> T-S with a Tylan<sup>®</sup> pellet or Component<sup>®</sup> T-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<sup>®</sup> T-S with a Tylan<sup>®</sup> pellet compared to animals treated with Component<sup>®</sup> T-S alone, with the maximum incidence of abscesses of 8% and 100%, respectively.

**5. TARGET ANIMAL SAFETY**

Target animal safety of Component<sup>®</sup> T-S and Component<sup>®</sup> T-H 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 pellet was safe for use in cattle. No further studies were required.

**6. HUMAN SAFETY**

Human safety is established for Component<sup>®</sup> T-S and Component<sup>®</sup> T-H by data in the parent application. No further studies were required for use of the tylosin pellet.

**7. AGENCY CONCLUSIONS**

Adequate data demonstrates the safe and effective use of a tylosin tartrate pellet added to Component<sup>®</sup> T-S and Component<sup>®</sup> T-H 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<sup>®</sup> T-S and Component<sup>®</sup> T-H. 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<sup>®</sup> T-S with Tylan<sup>®</sup> Box Label
2. Component<sup>®</sup> T-S with Tylan<sup>®</sup> 20 Dose Foil Pouch
3. Component<sup>®</sup> T-S with Tylan<sup>®</sup> Package Insert
4. Component<sup>®</sup> T-H with Tylan<sup>®</sup> Box Label
5. Component<sup>®</sup> T-H with Tylan<sup>®</sup> 20 Dose Foil Pouch
6. Component<sup>®</sup> T-H with Tylan<sup>®</sup> 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® T-S**

BRAND IMPLANTS FOR FEEDLOT STEERS

trenbolone acetate 140 mg with 29 mg tylosin tartrate as a local antibacterial



COMPONENT® T-S is a slow release anabolic agent containing trenbolone acetate, which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days.

**Contains:** 5 Cartridge Belts\* of 20 implants each. Each dose consists of 140 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

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

\* Patented by Ivy Laboratories, Inc. ANADA 200-224, Approved by FDA



100 IMPLANTS



**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) - 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.

COMPONENT is a registered trademark of Ivy Laboratories, Inc.  
Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for: **VetLife L.L.C.**, Overland Park, KS 66214, USA by Ivy Laboratories, Inc.

01 25 03 00

**COMPONENT®**  
**T-S**  
trenbolone acetate 140 mg  
with 29 mg tylosin tartrate  
as a local antibacterial  
FOR FEEDLOT STEERS

100 DOSES CARTON  
REDUCED TO 75%

- 01 BLACK STOP
- 02 SPECIAL
- 03 SPECIAL
- 04 YELLOW
- 05 BLACK
- 06 BLACK
- 07 BLACK
- 08 BLACK
- 09 BLACK
- 10 BLACK
- 11 BLACK
- 12 BLACK
- 13 BLACK
- 14 BLACK
- 15 BLACK
- 16 BLACK
- 17 BLACK
- 18 BLACK
- 19 BLACK
- 20 BLACK

Fold & Seal Area Print Optional

FOLD HERE

Front Panel



Bleed 1 color only

**COMPONENT<sup>®</sup> T-S**  
BRAND IMPLANTS FOR FEEDLOT STEERS

trenbolone acetate 140 mg with 29 mg tylosin tartrate as a local antibacterial

Bleed 1 color only



COMPONENT<sup>®</sup> T-S is a slow release anabolic agent containing trenbolone acetate, which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days.

**Contains:** One Cartridge Belt\* of 20 implants each sealed in a sanitary foil pouch. Each dose consists of 140 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

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

\* Patented by Ivy Laboratories, Inc. ANADA 200-224, Approved by FDA



**One 20-Dose Cartridge Belt**

Bleed 1 color only

Bleed 1 color only

IVY LABS.  
VETLIFE COMPONENT  
T-S with Tylan Foil Pouch  
3.136" x 9.562" - 4/15/98  
Mag Cyan Black



Fold & Seal Area Print Optional

Back Panel



Bleed 1 color only

Bleed 1 color only

**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) - 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.

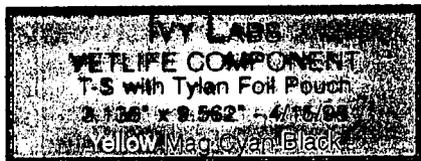
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NOT FOR HUMAN USE – KEEP OUT OF REACH OF CHILDREN**

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Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for: VetLife L.L.C., Overland Park, KS 66214, USA by Ivy Laboratories, Inc.  
01 25 02 00



Bleed 1 color only

Bleed 1 color only



- 18 CYAN
- 19 MAGENTA
- 20 YELLOW
- 21 SPECIAL
- 22 SPECIAL
- 23 BLACK STOP

Fold & Seal Area Print Optional

TEAR HERE

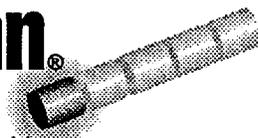
20 DOSES FOIL POUCH  
BACK

**COMPONENT**  
BRAND IMPLANTS



# T-S WITH Tylan

FOR FEEDLOT STEERS



trenbolone acetate USP 140 mg with  
29 mg tylosin tartrate as a local antibacterial

## 20 dose CARTRIDGE BELT\*

For use with the COMPONENT® One Gun™\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-S Implants for feedlot steers. Each dose of 8 pellets consists of 7 pellets containing a total of 140 mg of trenbolone acetate USP plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® T-S Implants are recommended for use in feedlot steers for IMPROVED FEED EFFICIENCY.

Manufactured by a non-sterilizing process.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days.

**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.

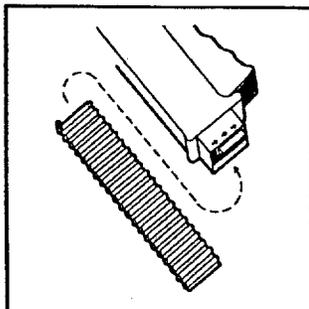
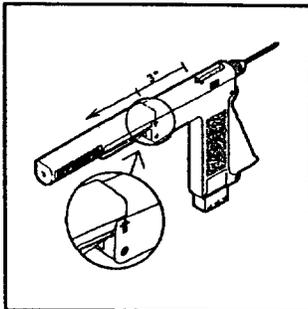
KEEP THIS AND ALL OTHER DRUGS  
OUT OF REACH OF CHILDREN.

Restricted Drug-Use Only As Directed (California)

### 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 alcohol or topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant into animal's eyes.

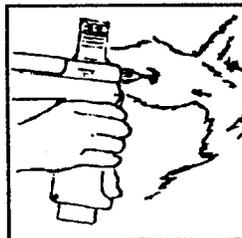
**Where to Implant**

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 and 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.

**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° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

ANADA 200-224, Approved by FDA

\*U.S. Patent No. 4,531,938  
 \*\*U.S. Patent Nos. 4,762,515 & 5,522,797 - Ivy Animal Health, Inc.  
 COMPONENT T-S 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.

**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® T-H**  
BRAND IMPLANTS FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg with 29 mg tylosin tartrate as a local antibacterial



COMPONENT T-H is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter.

**Contains:** 5 Cartridge Belts\* of 20 implants each. Each dose consists of 200 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

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

\* Patented by Ivy Laboratories, Inc. ANADA 200-224, Approved by FDA

100 IMPLANTS



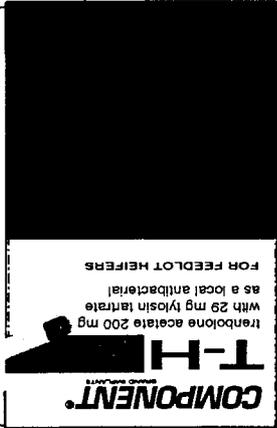
**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose - 11 pellets (entire contents of one cartridge) - in the ear subcutaneously. Any other site is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

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

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Manufactured for: **VetLife L.L.C.**, Overland Park, KS 66214, USA by Ivy Laboratories, Inc.

01 26 03 00

100 DOSES CARTON  
REDUCED TO 75%



Front Panel



Bleed 1 color only

Bleed 1 color only

# COMPONENT<sup>®</sup> T-H

BRAND IMPLANTS FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg with 29 mg tylosin tartrate as a local antibacterial



Fold & Seal Area Print Optional

TEAR HERE

- 18 C
- 22 M
- 23 K
- 24 Yellow
- 25 Yellow
- 26 Special
- 27 Black Stop

COMPONENT<sup>®</sup> T-H is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter.

**Contains:** One Cartridge Belt\* of 20 implants each sealed in a sanitary foil pouch. Each dose consists of 200 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

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

\* Patented by Ivy Laboratories, Inc. ANADA 200-224, Approved by FDA



One 20-Dose Cartridge Belt

Bleed 1 color only

Bleed 1 color only

IVY LABS  
 VETLIFE COMPONENT  
 T-H with Tylan Foil Pouch  
 3.136" x 9.562" - 4/15/98  
 Mag Cyan Black



Fold & Seal Area Print Optional

Back Panel



Bleed 1 color only

Bleed 1 color only

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose - 11 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.

**Storage Conditions:**

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

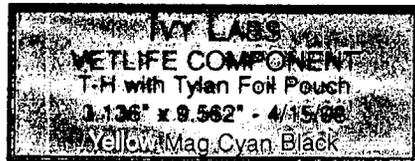
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Manufactured for: VetLife L.L.C., Overland Park, KS 66214, USA by Ivy Laboratories, Inc.  
01 26 02 00



Bleed 1 color only

Bleed 1 color only



Fold & Seal Area Print Optional



TEAR HERE

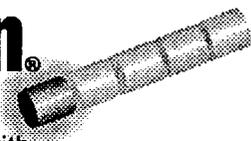
20 DOSES FOIL POUCH  
BACK

**COMPONENT**  
BRAND IMPLANTS

**VetLife**

# T-H WITH Tylan

FOR FEEDLOT HEIFERS



trenbolone acetate USP 200 mg with  
29 mg tylosin tartrate as a local antibacterial

## 20 dose CARTRIDGE BELT\*

For use with the COMPONENT® One Gun™\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-H Implants for feedlot heifers. Each dose of 11 pellets consists of 10 pellets containing a total of 200 mg of trenbolone acetate USP plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® T-H Implants are recommended for use in feedlot heifers for INCREASED RATE OF WEIGHT GAIN AND FEED EFFICIENCY.

Manufactured by a non-sterilizing process.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter.

**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.

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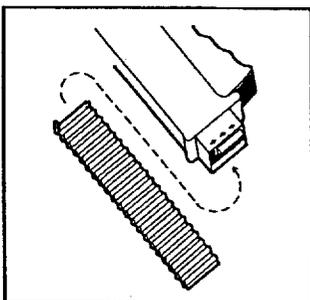
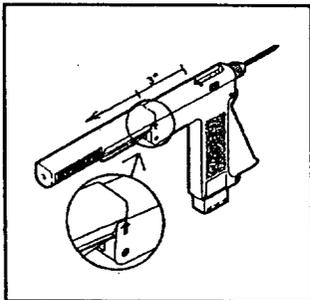
KEEP THIS AND ALL OTHER DRUGS  
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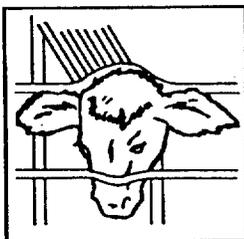
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**Restrain the Animal**

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**Prepare the Implant Site**

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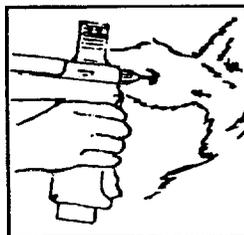
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