

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

Elanco™

Component™

TE-IS with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

FOR GROWING BEEF STEERS FED IN CONFINEMENT FOR SLAUGHTER

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20-dose Cartridge Belt

Use with a Component Planter

DESCRIPTION:

Each cartridge belt holds 20 doses of Component TE-IS with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 16 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE:

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

Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter.

Safety and effectiveness following re-implantation 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 established.

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

WARNING:

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. 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 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

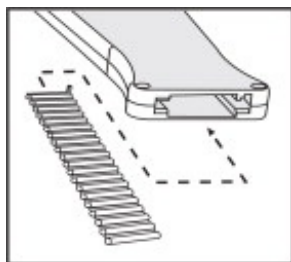
Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

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.

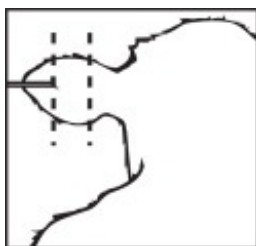
Where to Implant

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 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. 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.

Storage Conditions

Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity. Use before the expiration date printed on the foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-221

Manufactured by a non-sterilizing process.

Component TE-IS with Tylan is covered by U.S. Patent No. 5,874,098

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

Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, 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>.

April 2023

PA104025X AH0508

Principal Display Panel - Carton Label

Elanco[™]

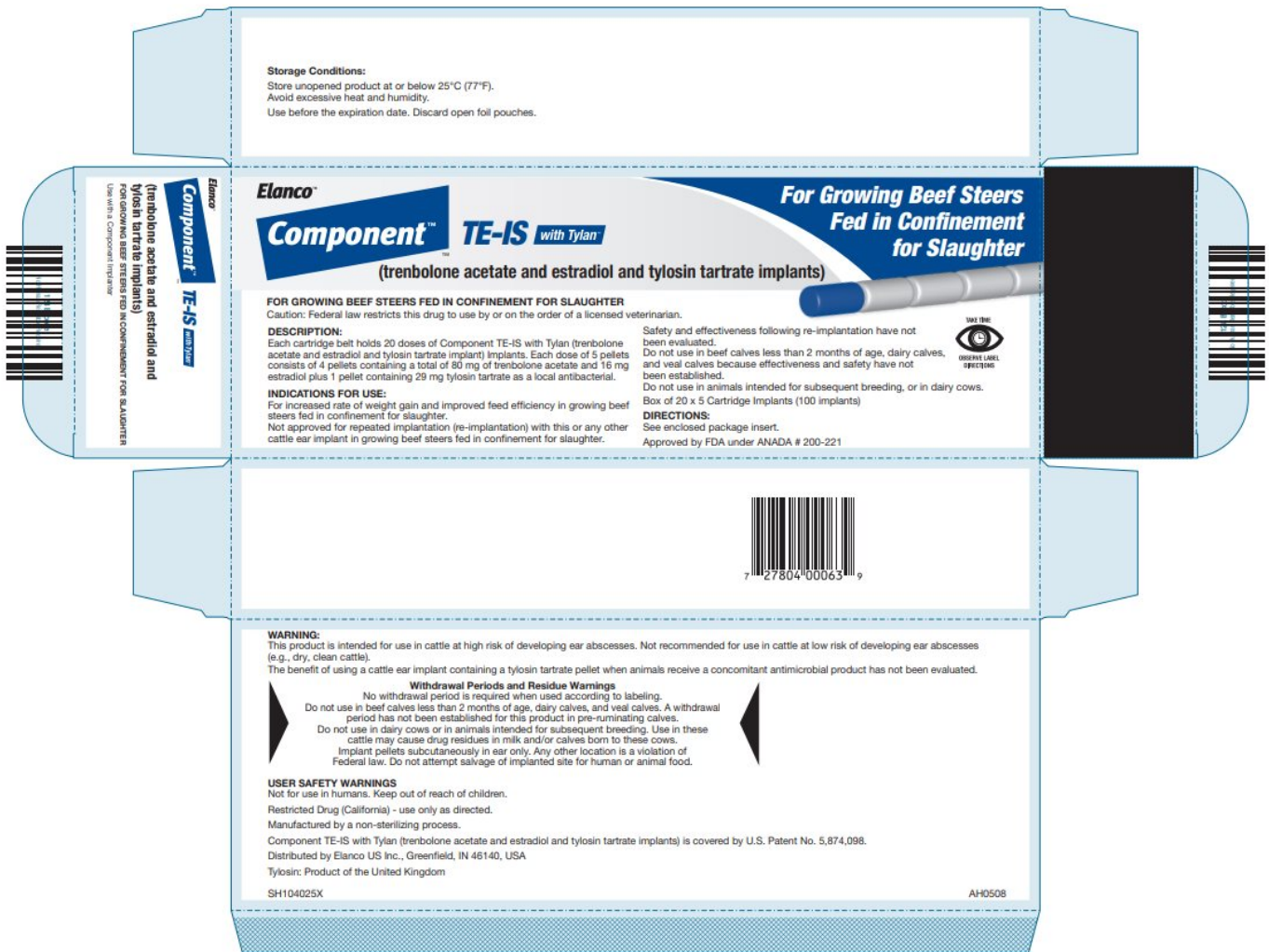
Component[™]

[™]

TE-IS with Tylan[™]

(trenbolone acetate and estradiol and tylosin tartrate implants)

***For Growing Beef Steers
Fed in Confinement
for Slaughter***



Principal Display Panel - Cartridge Label

Elanco™

Component™

™

TE-IS with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

**For Growing Beef Steers
Fed in Confinement
for Slaughter**

**One 20-Dose
Cartridge Belt**

Elanco

Component™ TE-IS with Tylan
(trenbolone acetate and estradiol and tylosin tartrate implants)

For Growing Beef Steers Fed in Confinement for Slaughter

FOR GROWING BEEF STEERS FED IN CONFINEMENT FOR SLAUGHTER
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
Each cartridge belt holds 20 doses of Component TE-IS with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) implants. Each dose of 5 pellets consists of 4 pellets containing a total of 60 mg of trenbolone acetate and 18 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE:
For increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter. Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter. Safety and effectiveness following re-implantation 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 established. Do not use in animals intended for subsequent breeding, or in dairy cows.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Manufactured by a non-sterilizing process. Approved by FDA under ANADA # 200-221

One 20-Dose Cartridge Belt
FL104025A

TEAR HERE

WARNING:
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. 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 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. Restricted Drug (California) - use only as directed. Important: Read the enclosed instruction brochures. Use as illustrated with a CAREFUL, CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS. Storage Conditions: Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity. Use before the expiration date. Discard open foil pouches.

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FL104025B AH0508

PURCHASE SEAL 20 IMPLANTS
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EXP
LOT

TEAR HERE

Principal Display Panel - Component TE-IS with Tylan Package Insert

Elanco™

Component™

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TE-IS with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

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20-dose Cartridge Belt

Use with a Component Implanter

Elanco

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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 calves born to these cows.

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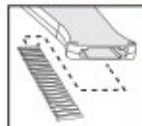
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April 2023

PA104025X

AH0508

COMPONENT TE-IS WITH TYLAN

trenbolone acetate, estradiol, tylosin tartrate implant

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-0508
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trenbolone acetate (UNII: RUD5Y4SV0S) (trenbolone - UNII:P53R4420TR)	trenbolone acetate	80 mg
estradiol (UNII: 4TI98Z838E) (estradiol - UNII:4TI98Z838E)	estradiol	16 mg
tylosin tartrate (UNII: 5P4625C51T) (tylosin - UNII:YEF4JXN031)	tylosin tartrate	29 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0508-2	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	ANADA200221	12/09/2013	

Labeler - Elanco US Inc. (966985624)

Revised: 1/2025

Elanco US Inc.