

**COMPONENT E-C WITH TYLAN- progesterone, estradiol benzoate, tylosin tartrate implant**  
**Elanco US Inc.**

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**Elanco™**

**Component™**

**E-C with Tylan™**

**(progesterone and estradiol benzoate and tylosin tartrate implant)**

**BEEF CALVES 45 DAYS OF AGE AND OLDER**

**AND WEIGHING UP TO 400 LBS**

Each implant consists of 100 mg progesterone USP and 10 mg estradiol benzoate and 29 mg tylosin tartrate

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

**IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS**

**Use with a Component Implanter**

**DESCRIPTION:**

Each cartridge belt holds 20 doses of Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 100 mg progesterone USP and 10 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

**INDICATIONS FOR USE:**

For increased rate of weight gain in beef calves 45 days of age and older and weighing up to 400 lbs.

This implant is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant as safety and effectiveness has not been evaluated.

Do not use in calves less than 45 days of age or veal calves because effectiveness and safety have not been evaluated.

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

**DIRECTIONS:**

Administer 1 implant - the entire contents of one cartridge cell (5 pellets) - subcutaneously in the back of the middle third of the ear. Study and carefully follow at all times the "IMPLANTING INSTRUCTIONS" presented below, 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.

### **Withdrawal Periods and Residue Warnings**

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 45 days of age, dairy calves, and veal calves. Do not use in bull calves intended for reproduction. 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 in 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

### **ANIMAL SAFETY WARNINGS:**

Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C with Tylan Implants.

### **WARNINGS:**

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.

### **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.



### **Prepare the Implant Site**

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton or brush 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 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. 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 lead to undesirable side effects such as bulling, rectal and vaginal prolapse, etc., as noted in the WARNINGS.

### **STORAGE CONDITIONS:**

Store at controlled room temperature 15° to 30°C (59° to 86°F) DO NOT refrigerate - avoid excessive heat and humidity. Discard open foil pouches.

Approved by FDA under NADA # 110-315

Manufactured by a non-sterilizing process.

Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implants) 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.

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

Tylosin: Product of United Kingdom

Revised: June 2023

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### **Principal Display Panel - Component E-C With Tylan Cartridge Label**

**Elanco™**

**Component™**

™

**E-C with Tylan™**

**(progesterone and estradiol benzoate and tylosin tartrate implants)**

**BEEF CALVES 45 DAYS OF AGE AND OLDER**

**AND WEIGHING UP TO 400 LBS**



## Principal Display Panel - Component E-C With Tylan Pouch Label

**Elanco™**

**Component™**

™

**E-C with Tylan™**

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**IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS**

**Component E-C**

Each implant consists of 100 mg progesterone USP and 10 mg estradiol benzoate and 29 mg tylosin tartrate.

**IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS**

**INDICATIONS FOR USE:** For increased rate of weight gain in beef calves 45 days of age and older and weighing up to 400 lbs.

**CONTRAINDICATIONS:** Do not use in calves less than 45 days of age or real calves because effectiveness and safety have not been established.

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

**WARNINGS:** Do not use in beef calves less than 45 days of age, dairy calves, and real calves. Do not use in bull calves intended for reproduction. 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 in 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**

**ANIMAL SAFETY WARNINGS:** Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, uterine development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C with Tylan implants.

**WARNINGS:** 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 established.

**IMPLANTING INSTRUCTIONS:**


**Load 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.

**Prepare the Implant Site**  
Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton or brush which has been soaked with topical germicidal solution. Follow manufacturer's directions on the product label for strength and concentration 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 and at least a needle length away from the intended deposition site. Avoid injuring the large artery, vein 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.



See the space between the lines and the printing

**Insert 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 leakage or crushing of pellets if otherwise forced into contact with rough 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 lead to undesirable side effects such as bulling, rectal and vaginal prolapse, etc., as noted in the WARNINGS.

**STORAGE CONDITIONS:** Store at controlled room temperature 15° to 30°C (59° to 86°F). DO NOT refrigerate—avoid excessive heat and humidity. Discard open foil pouches.

Approved by FDA under NADA # 110-215

Manufactured by a non-sterilizing process.

Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implants) is covered by U.S. Patent No. 5,876,288

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

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Tylanin, Product of United Kingdom

(Revised: June 2023)

**Principal Display Panel - Component E-C With Tylan Carton Label**

**Elanco™**

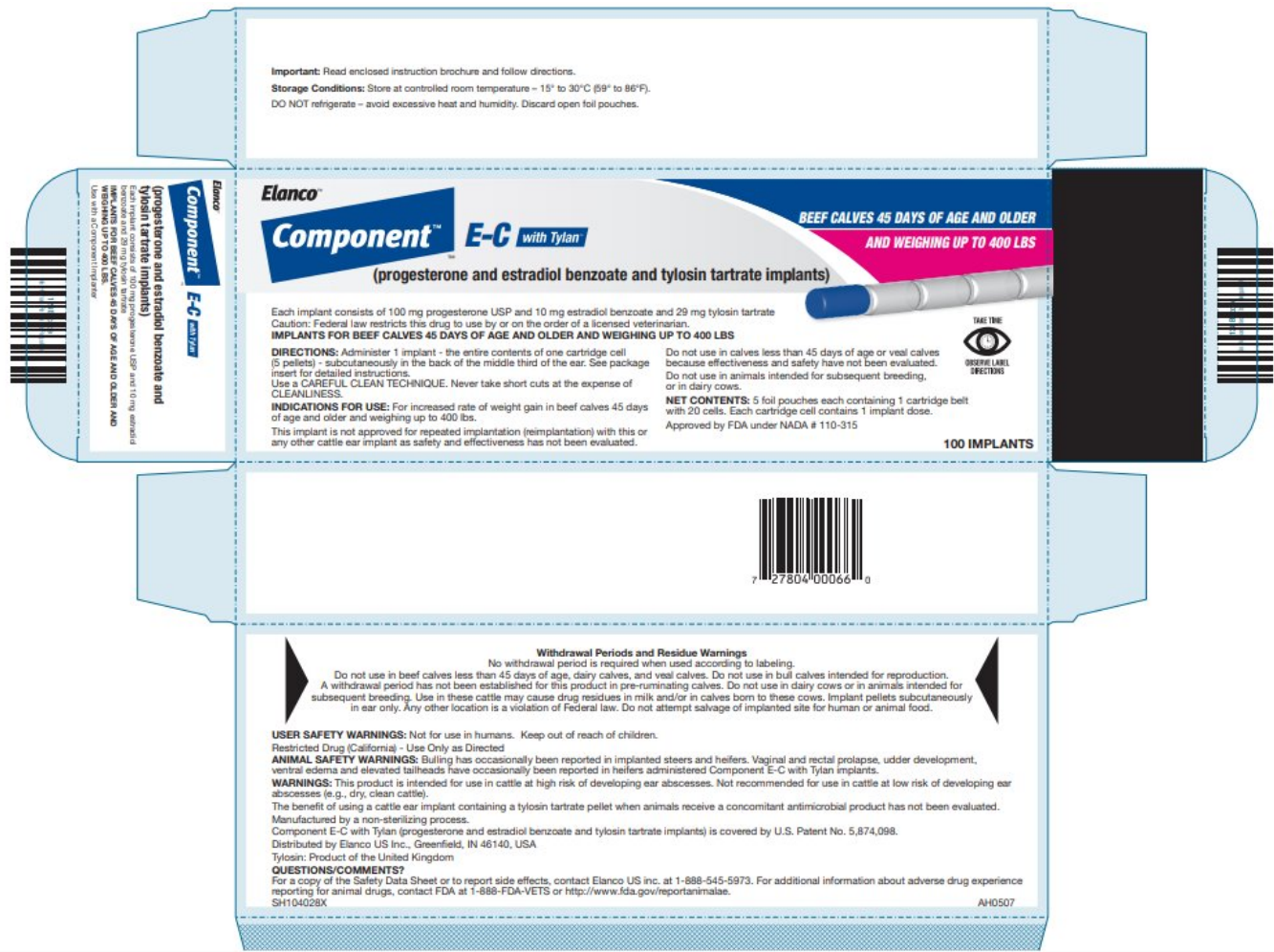
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## COMPONENT E-C WITH TYLAN

progesterone, estradiol benzoate, tylosin tartrate implant

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:58198-0507
<b>Route of Administration</b>	SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>progesterone</b> (UNII: 4G7DS2Q64Y) (progesterone - UNII:4G7DS2Q64Y)	progesterone	100 mg
<b>estradiol benzoate</b> (UNII: 1S4CJB5ZGN) (estradiol - UNII:4TI98Z838E)	estradiol benzoate	10 mg
<b>tylosin tartrate</b> (UNII: 5P4625C51T) (tylosin - UNII:YEF4JXN031)	tylosin tartrate	29 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0507-2	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
NADA	NADA110315	12/09/2013	

**Labeler** - Elanco US Inc. (966985624)

Revised: 12/2023

Elanco US Inc.