

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

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.

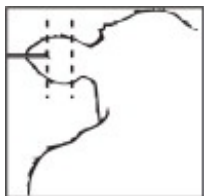
Where to Implant

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

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

Tylosin: Product of United Kingdom

Revised: June 2023

PA104028X AH0507

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

Elanco™

Component™

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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™

(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

Component E-C

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

Use with a Component Implanter

DESCRIPTION: Each cartridge will hold 20 doses of Component E-C with Tylan progesterone and estradiol benzoate and tylosin tartrate implant pellets. Each dose of 4 pellets contains a total of 100 mg progesterone USP and 10 mg estradiol benzoate plus 1 pellet containing 20 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.

The 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 real 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 (6 pellets) - subcutaneously in the back of the middle third of the ear. Study and carefully follow all 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 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 evaluated.

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 for disinfection of contact brush, and disinfection of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the ear 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.

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 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 swelling, rectal and vaginal prolapse, etc., as listed 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 implant is covered by U.S. Patent No. 5,874,286

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Distributed by Elanco US Inc., Greenfield, IN 46160, USA

Tylan: Product of United Kingdom

(Revised: June 2023)

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

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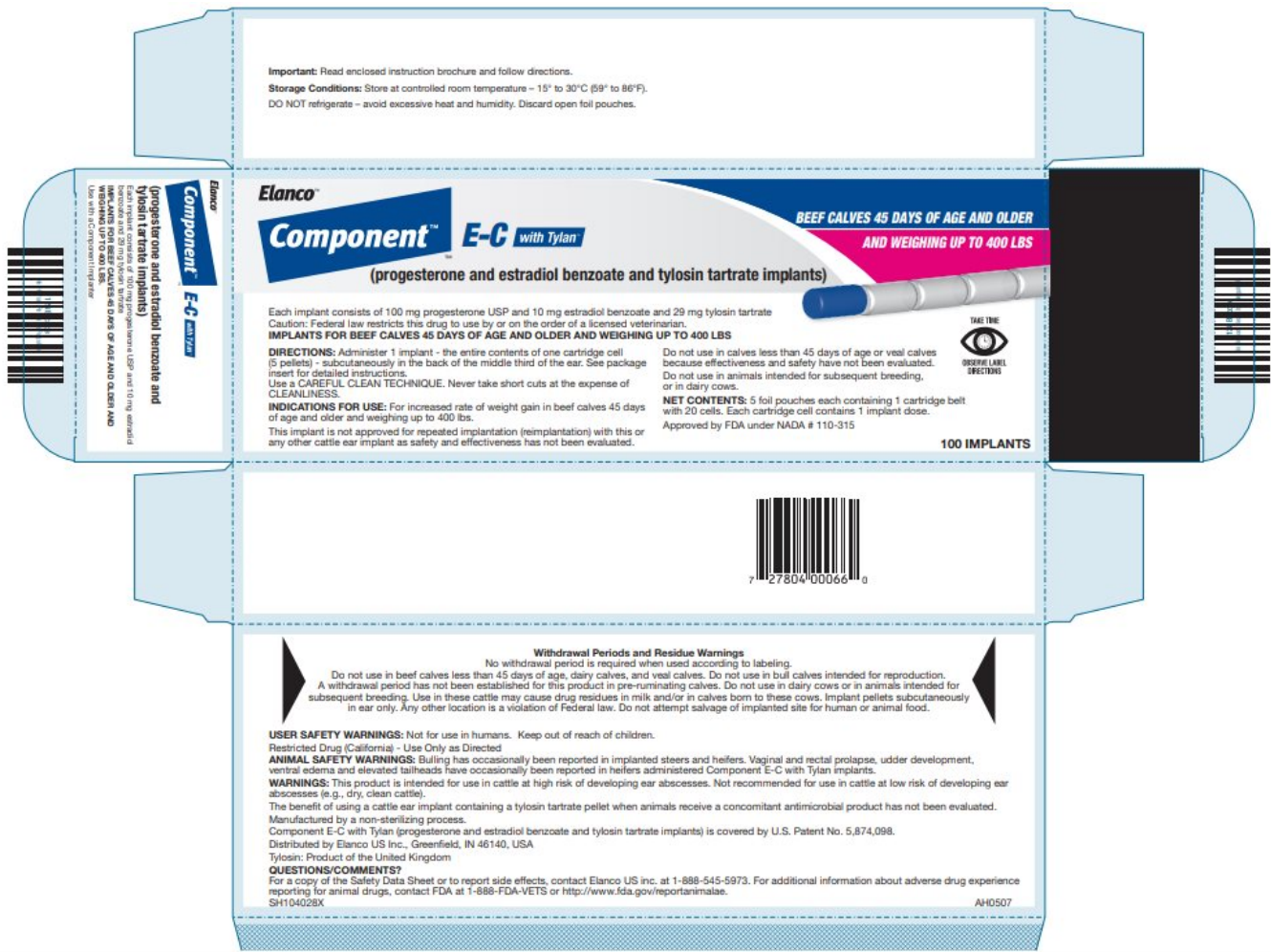
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E-C with Tylan™

(progesterone and estradiol benzoate and tylosin tartrate implants)

BEEF CALVES 45 DAYS OF AGE AND OLDER

AND WEIGHING UP TO 400 LBS



COMPONENT E-C WITH TYLAN

progesterone, estradiol benzoate, tylosin tartrate implant

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
progesterone (UNII: 4G7DS2Q64Y) (progesterone - UNII:4G7DS2Q64Y)	progesterone	100 mg
estradiol benzoate (UNII: 1S4CJB5ZGN) (estradiol - UNII:4TI98Z838E)	estradiol benzoate	10 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:58198-0507-2	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: 1/2025

Elanco US Inc.