

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

DESCRIPTION:

Each cartridge belt holds 20 doses of Component E-S with Tylan (progesterone and estradiol and tylosin implant) Implants. Each dose of 9 pellets consists of 8 pellets containing a total of 200 mg progesterone USP and 20 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. Component E-S (progesterone and estradiol implant) Implants are recommended for use in steers weighing 400 lbs or more for INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

DOSAGE:

Administer 1 implant per animal according to the following instructions.

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. Implant one dose — 9 pellets (entire contents of one cartridge cell) — 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.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

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

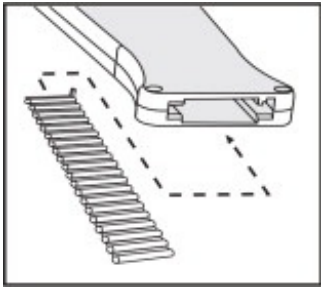
CAUTION:

Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

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.

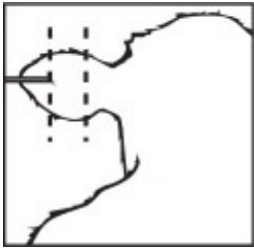
Where to Implant

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 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 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 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 and may lead to undesirable side effects such as noted in the CAUTION.

Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

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.

NADA 110-315, Approved by FDA

Manufactured by a non-sterilizing process.

Component E-S with Tylan (progesterone and estradiol and tylosin implant) 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.

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

Tylosin: Product of the United Kingdom

To report adverse events, access medical information, or to obtain additional product information, call 1-800-428-4441

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

Elanco™

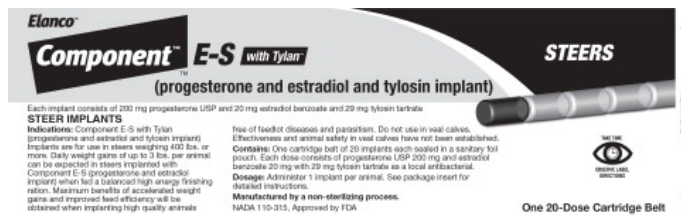
Component™

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E-S with Tylan™

(progesterone and estradiol and tylosin implant)

STEERS



EXP
LOT

Principal Display Panel - Component E-S With Tylan Pouch Label

Elanco™

Component™

™

E-S with Tylan™

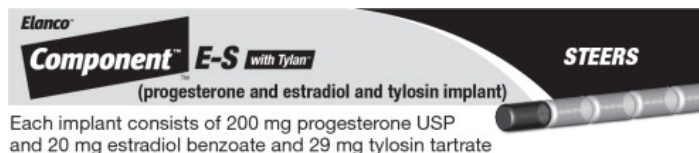
(progesterone and estradiol and tylosin implant)

STEERS

Each implant consists of 200 mg progesterone USP and 20 mg estradiol benzoate and 29 mg tylosin tartrate

STEER IMPLANTS

20 dose Cartridge Belt



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STEER IMPLANTS

20 dose Cartridge Belt

Use with a Component Implanter
For Use In Animals Only

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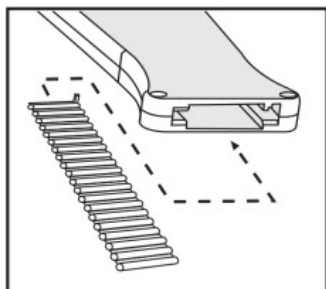
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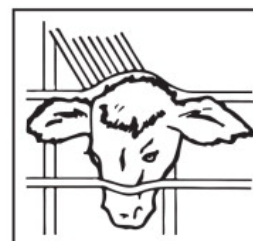
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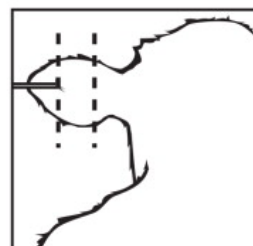
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Tylosin: Product of the United Kingdom

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AH0328

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

Elanco™

Component™

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E-S with Tylan™

(progesterone and estradiol and tylosin implant)

STEERS

Important: Read enclosed instruction brochure and follow directions.
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.



Each implant consists of 200 mg progesterone USP and 20 mg estradiol benzoate and 29 mg tylosin tartrate

STEER IMPLANTS

Indications: Component E-S with Tylan (progesterone and estradiol and tylosin implant) Implants are for use in steers weighing 400 lbs. or more. Daily weight gains of up to 3 lbs. per animal can be expected in steers implanted with Component E-S (progesterone and estradiol implant) when fed a balanced high energy finishing ration. Maximum benefits of accelerated weight gains and improved feed efficiency will be obtained when implanting high quality animals free of feedlot diseases and parasitism. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

Contents: 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of progesterone USP 200 mg and estradiol benzoate 20 mg with 29 mg tylosin tartrate as a local antibacterial.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions.

NADA 110-315, Approved by FDA



100 IMPLANTS



Use with a Component Implanter

WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.
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▲ A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. ▼

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Caution: Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

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

Manufactured by a non-sterilizing process.

Component E-S with Tylan (progesterone and estradiol and tylosin implant) is covered by U.S. Patent No. 5,874,098.

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

Tylosin: Product of the United Kingdom

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SH10095X

Each implant consists of 200 mg progesterone USP and 20 mg estradiol benzoate and 29 mg tylosin tartrate

STEER IMPLANTS



AH0328

COMPONENT E-S WITH TYLAN

progesterone, estradiol benzoate, tylosin tartrate implant

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58 198-0328
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
progesterone (UNII: 4G7DS2Q64Y) (progesterone - UNII:4G7DS2Q64Y)	progesterone	200 mg
estradiol benzoate (UNII: 1S4CJB5ZGN) (estradiol - UNII:4TI98Z838E)	estradiol benzoate	20 mg
tylosin tartrate (UNII: 5P4625C51T) (tylosin - UNII:YEF4JXN031)	tylosin tartrate	29 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 800 (UNII: UH6KR4953D)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0328-2	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: 8/2018

Elanco US Inc.