

Approval Date: OCT. 28 2001

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION

ANADA 200-367

SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120
(Trenbolone Acetate and Estradiol)

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501

FREEDOM OF INFORMATION SUMMARY

SYNOVEX T40 Ear Implant for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

SYNOVEX T80 Ear Implant for Steers Fed in Confinement for Slaughter

SYNOVEX T120 Ear Implant for Steers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-367
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501
Drug Labeler Code: 000856
- c. Established Names: Trenbolone Acetate and Estradiol
- d. Propriety Names: SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2477
- f. How Supplied: SYNOVEX T40: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 2 pellets containing 40 mg trenbolone acetate and 8 mg estradiol.
- SYNOVEX T80: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 4 pellets containing 80 mg trenbolone acetate and 16 mg estradiol.
- SYNOVEX T120: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 6 pellets containing 120 mg trenbolone acetate and 24 mg estradiol.
- g. How Dispensed: OTC

- n. Effect of Supplement: This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

2. DRUG EFFECTIVENESS:

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent abbreviated new animal drug applications for SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent abbreviated new animal drug applications for SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent abbreviated new animal drug applications for SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

5. AGENCY CONCLUSIONS:

The information submitted in support of this ANADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status

remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. 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.

No patent information was submitted with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

SYNOVEX T40 Carton Label
SYNOVEX T40 Pouch (Front and Back)
SYNOVEX T80 Carton Label
SYNOVEX T80 Pouch (Front and Back)
SYNOVEX T120 Carton Label
SYNOVEX T120 Pouch (Front and Back)

25" 6.75" 25"

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

AMADA 240-367 Approved by FDA NDC 6591-001-01

Synovex T80 (trenbolone acetate and estradiol) is a 30-day implant containing 30 mg trenbolone acetate and 10 mg estradiol. Each implant consists of two cylindrical pellets. For implants see procedure for implantation.

INDICATIONS FOR USE: Increase rate of weight gain and improve feed efficiency in steers. Show release of stress. Do not use in pregnant steers. Use only in steers that are not lactating or nursing calves.

DOSAGE: One implant containing 30 mg trenbolone acetate and 10 mg estradiol is administered to each animal. The 4 pellets that make up the Synovex T80 are contained in two cylindrical pellets. The two pellets are administered to the steer exclusively with Synovex implant procedure.

WARNING: Not to be used in pregnant steers. Not to be used in lactating steers. Do not use in pregnant steers. Do not use in lactating steers. Do not use in lactating steers.

ROUTE OF ADMINISTRATION: The implant is placed under the skin of the neck area. It is inserted by means of a special applicator. For details see procedure for implantation.

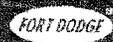
NOTE: Never sacrifice careful clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature (20°C/68°F). Do not use after expiration date printed on the label.

Keep this and all other drugs out of the reach of children.

Resistant Drug Containing Steer Implant

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA



Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

NET CONTENTS:

One pouch contains ten 10-dose cartridges (100 implants)

NOTE: Leave 0.4375" white space on bottom of front and back.

375" 375" 8.875" 25"

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

SYNOVEX® T80
(trenbolone acetate and estradiol)

AMADA 240-367 Approved by FDA NDC 6591-001-01

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Resistant Drug Containing Steer Implant

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

404-0000

ALL ELECTRONIC ARTWORK IS THE PROPERTY OF AND MUST BE RETURNED TO FORT DODGE ANIMAL HEALTH

PRINT ON 1

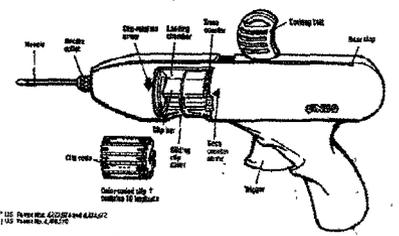
ON ANGLE

404-0000

Brand Name	3
Device	101
Product ID#	80822
Manufacturer	SYNOVEX T80
Product Name	SYNOVEX T80
Formulation	10-Dose
Quantity	220
Dimensions	6.64 x 17.76
File Path	80822/80822
To Date	200303 14
Rev Level	1

Part No.	6	Type/Size	026170-0100	SYNOVEX
System	SYNOVEX	Model No.	700	SYNOVEX
Product No.	026170	Manufacturer	026170-0100	SYNOVEX
Part Name	SYNOVEX	Part No.	026170-0100	SYNOVEX
Product Name	SYNOVEX	Part No.	026170-0100	SYNOVEX

SYNOVEX[®] SX10[®] Gun[®]



HOW TO IMPLANT SYNOVEX[®] T120 Implants

IMPLANTS
For Use With Any Synovex Gun.

Study the following instructions carefully. Then proceed step by step, using the technique described herein. Many heifers can be implanted per hour by an experienced team. One operator of which should be assigned to do nothing but the implantation. Care should be taken to assure the health of the person administering the implant. Use clean and dry sanitary instruments are used.

SYNOVEX[®] T120

SYNOVEX[®] T120 is recommended for steers fed in confinement for slaughter. When used on pregnant steers, the implant should be removed 30 days prior to calving. The implant should be removed 30 days prior to calving. The implant should be removed 30 days prior to calving.

SYNOVEX[®] T120

SYNOVEX[®] T120 is recommended for steers fed in confinement for slaughter. When used on pregnant steers, the implant should be removed 30 days prior to calving. The implant should be removed 30 days prior to calving. The implant should be removed 30 days prior to calving.

STEP 1 Loading The SX10 Gun

Load the SX10 gun with the cartridge and load the SX10 gun. The SX10 gun is loaded with the cartridge and the SX10 gun is loaded with the cartridge.

STEP 2 Restraint

The restrained steer should be held in a position where the neck of the steer is about 10 degrees from the vertical. The restrained steer should be held in a position where the neck of the steer is about 10 degrees from the vertical.

STEP 3 Implant Site

On the left side of the neck, 2-3 inches below the ear, the implant site should be marked. The implant site should be marked on the neck of the steer, 2-3 inches below the ear.

STEP 4 Insert Needle

Just before passing the needle with the implant, remove the cap by pulling the handle of the needle. The needle should be inserted into the implant site.

STEP 5 Implantation

Push the SX10 gun forward until the needle is fully inserted. The SX10 gun should be pushed forward until the needle is fully inserted.

STEP 6 Injection

When the needle is completely inserted, the SX10 gun should be pulled back. The SX10 gun should be pulled back when the needle is completely inserted.

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER
SYNOVEX[®] T120
 (trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX[®] T120

(trenbolone acetate and estradiol)

ANADA 200-987
Approved by FDA

WDC 0345-5/0141

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 6 Pellets

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER
SYNOVEX[®] T120
 (trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

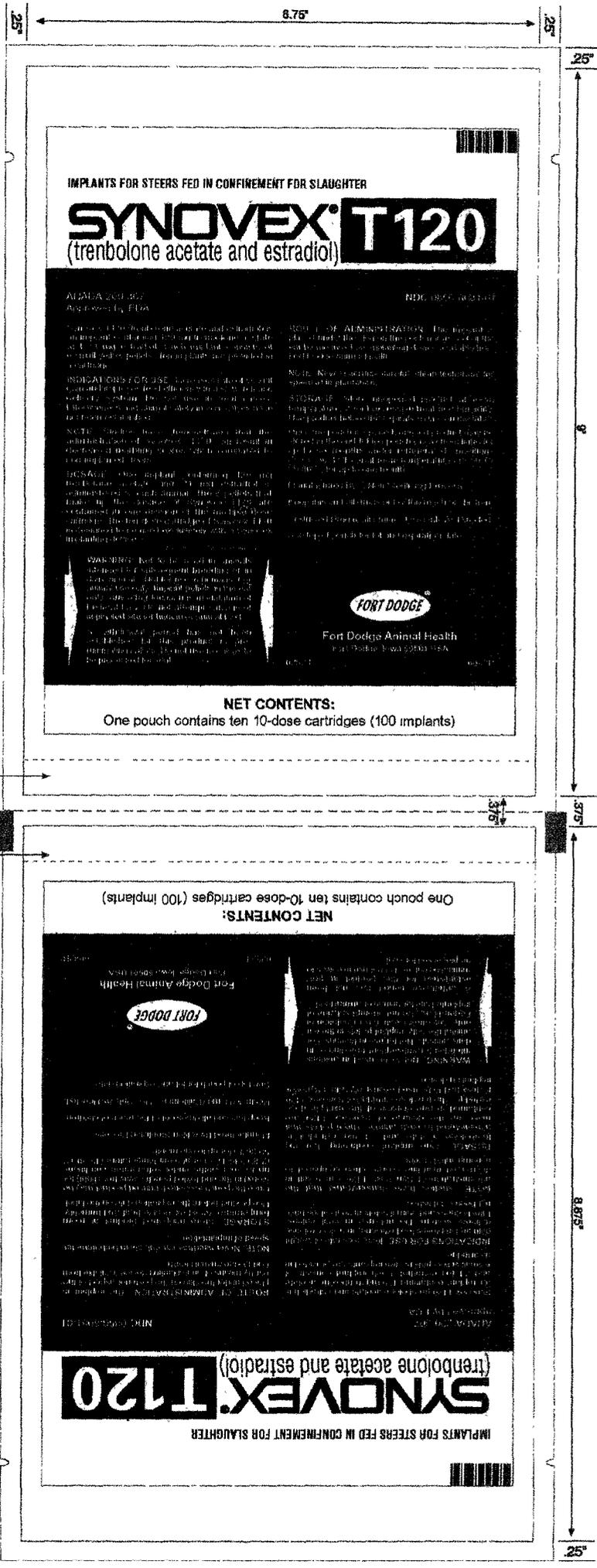
SYNOVEX[®] T120

(trenbolone acetate and estradiol)

NOTE: THE FOLLOWING INFORMATION IS FOR INFORMATIONAL PURPOSES ONLY. IT IS NOT INTENDED TO BE USED AS A SUBSTITUTE FOR THE INFORMATION CONTAINED IN THE PRODUCT LABELING.

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 6 Pellets

Open here for implanting instructions



IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX T120

(trenbolone acetate and estradiol)

ATLANTA 280 367 NDC 0822 1120 10
 Approved by FDA

Contains 100 implants in one pouch. Each implant is 10 mm long and 2 mm wide. Each implant is 10 mm long and 2 mm wide. Each implant is 10 mm long and 2 mm wide.

ROUTE OF ADMINISTRATION: The implants are administered by intramuscular injection into the neck muscle of the steer. The implants are administered by intramuscular injection into the neck muscle of the steer.

INDICATIONS FOR USE: Synovex T120 implants are indicated for the treatment of steers fed in confinement for slaughter. The implants are indicated for the treatment of steers fed in confinement for slaughter.

NOTE: New treatment methods are being developed for the control of disease in steers. The implants are indicated for the treatment of steers fed in confinement for slaughter.

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CAUTION: The implants are indicated for the treatment of steers fed in confinement for slaughter. The implants are indicated for the treatment of steers fed in confinement for slaughter.

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WARNINGS: Red to be used in animals. The implants are indicated for the treatment of steers fed in confinement for slaughter. The implants are indicated for the treatment of steers fed in confinement for slaughter.

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Fort Dodge Animal Health
 Fort Dodge, Iowa 50501 USA

NET CONTENTS:

One pouch contains ten 10-dose cartridges (100 implants)

NOTE: Leave 0.4375" white space on bottom of front and back.

FORT DODGE
ANIMAL HEALTH

5
 Revised

Operator: SN
 Date: 082264
 Product ID: 0022
 Revision: 1.022
 Synovex T120
 7-dose form
 10-10 Dose
 Form: Synovex
 220
 Trenbolone
 4-54 x 17-75
 V-187
 60226/0226
 280403 NI
 NY Label
 Y

40608210
 PMS 512

ALL INFORMATION CONTAINED HEREIN IS THE
 PROPERTY OF FORT DODGE ANIMAL HEALTH.

SYNOVEX T120

(trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

ATLANTA 280 367 NDC 0822 1120 10
 Approved by FDA

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