

REVALOR-IS- trenbolone acetate and estradiol implant
Merck Sharp & Dohme Corp.

Revalor®-IS
(trenbolone acetate and estradiol implants)

For Growing Beef Steers
Fed In Confinement
For Slaughter

DESCRIPTION

Revalor®-IS is an implant containing 80 mg of trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

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.

DIRECTIONS

The cartridge is designed to be used with a special implanting tool.

The special implanting tool is available from Intervet Inc. Ten doses (implants) are in each cartridge. The implant is placed under the skin on the posterior aspect of the ear (see **SITE OF IMPLANTATION** and **METHOD OF USE** sections).

See **Page 2, DIRECTIONS** for more detailed implantation directions.

With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

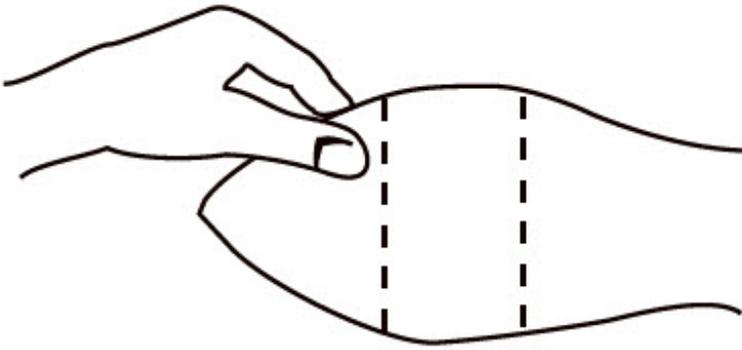


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of 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. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

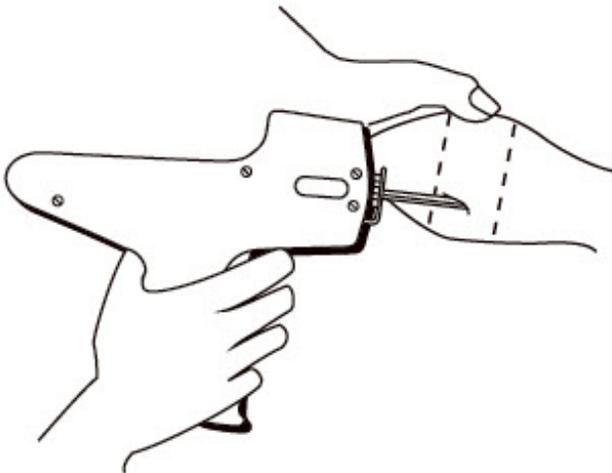


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the

- pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
 8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
 9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.

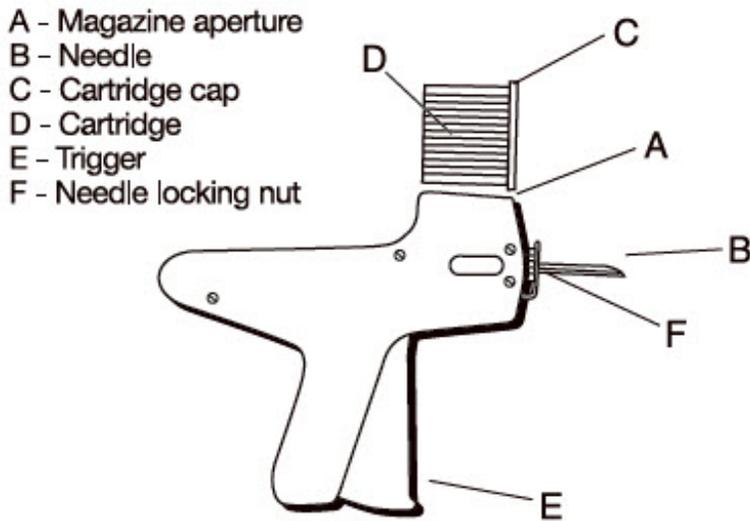


Fig. 3 - Diagram of the Implanter and Cartridge

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.

STORAGE CONDITIONS

Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity. Use product before the expiration date printed on the carton labeling and on the cartridge pouch. Opened cartridges may be stored in the foil pouch protected from light in the refrigerator (2-8°C/36-47°F) for up to 6 months.

HOW SUPPLIED

Box of 10 cartridges, each containing 10 implants per cartridge (100 implants total).

QUESTIONS/COMMENTS?

For a copy of the Safety Data Sheet or to report side effects, contact Merck Animal Health Technical Services at 1-800-211-3573. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc (d/b/a Merck Animal Health)
Madison, NJ 07940

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Restricted Drug (California) — use only as directed.

Approved by FDA under NADA # 140-897

Rev. 03/2023

166104 R4

Revalor is a registered trademark of Intervet Inc. or an affiliate.

PRINCIPAL DISPLAY PANEL - 10 x 10 Cartridge Implant Box

Revalor[®]-IS
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For Growing Beef Steers
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Box of 10 x 10 Cartridge Implants
(100 Implants)

Manufactured by a non-sterilizing process

MERCK
Animal Health

144x107x77mm
PSA020AD4 01 R0
C M Y K
L634
x=5 y=50

Revalor[®]-IS

(trenbolone acetate and estradiol implants)



For Growing Beef Steers
Fed In Confinement
For Slaughter

Box of 10 x 10 Cartridge Implants
(100 Implants)



Manufactured by a non-sterilizing process



LOT
EXP

Imprint area
lacquer- and color-free

Made in Austria by:
Intervet GmbH
Distributed by:
Intervet Inc (d/b/a Merck Animal Health)
Madison, NJ 07940

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Rev. 04/2023



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Box of 10 x 10 Cartridge Implants
(100 Implants)

Manufactured by a non-sterilizing process

Revalor[®]-IS

(trenbolone acetate and estradiol implants)



167634 R4

DESCRIPTION

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INDICATIONS FOR USE:

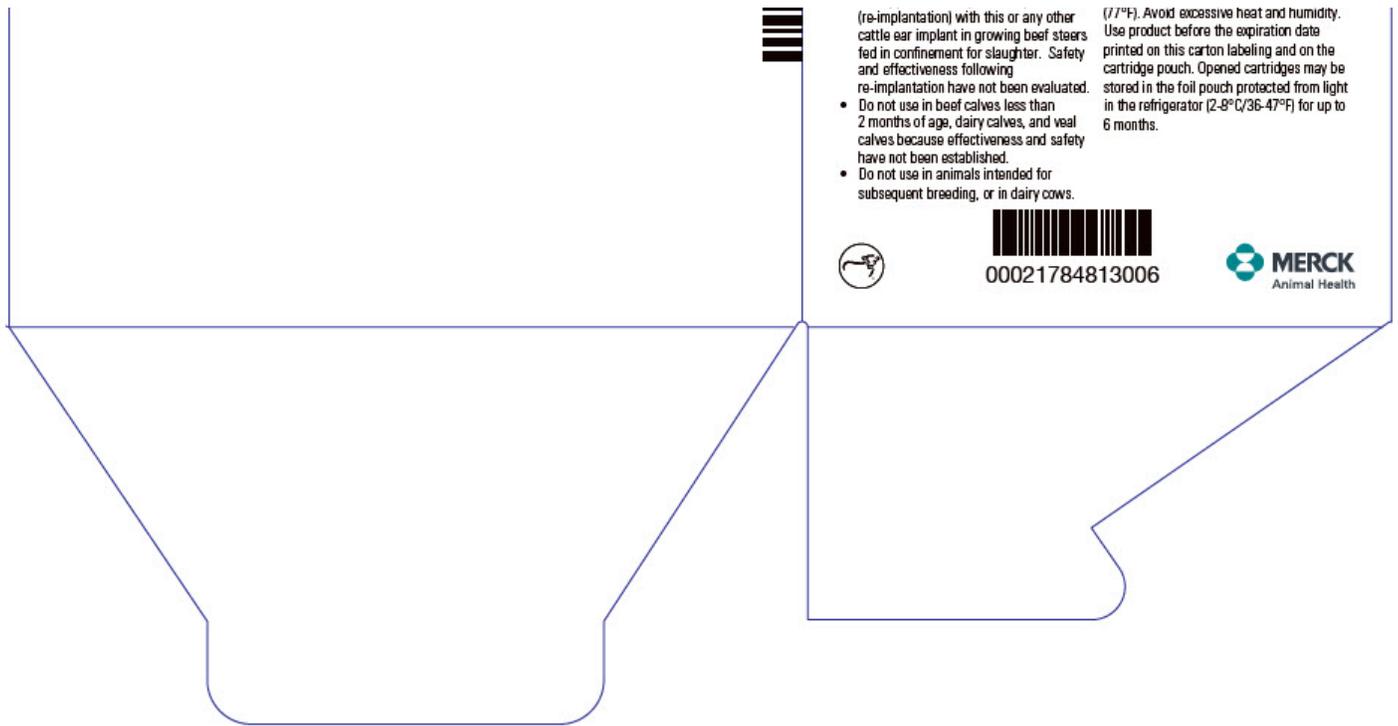
- For increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter
- Not approved for repeated implantation

DIRECTIONS

See enclosed package insert.

STORAGE CONDITIONS

Store unopened product at or below 25°C



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REVALOR-IS

trenbolone acetate and estradiol implant

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-022
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-022-01	10 in 1 BOX		
1		10 in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140897	11/27/1991	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Intervet GESMBH		303380992	MANUFACTURE

Revised: 11/2023

Merck Sharp & Dohme Corp.