

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

Revalor[®]-XS
(trenbolone acetate and estradiol)

For Steers
Fed In Confinement
For Slaughter

DESCRIPTION

Revalor[®]-XS (trenbolone acetate, CAS Registry Number 10161-34-9, and estradiol, CAS Registry Number 50-28-2) is an implant containing 200 mg of trenbolone acetate and 40 mg estradiol. Each implant consists of 10 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS FOR USE

This product contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain and improves feed efficiency for up to 200 days in steers fed in confinement for slaughter.

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

DOSAGE

One implant containing 200 mg trenbolone acetate and 40 mg estradiol is administered to each animal. The 10 pellets which make up the dosage of Revalor[®]-XS are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

ROUTE OF ADMINISTRATION

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.

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.

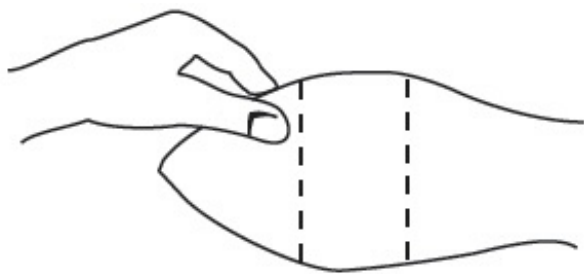


Fig. 1 - Ear of Bovine Ready for Implantation

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.

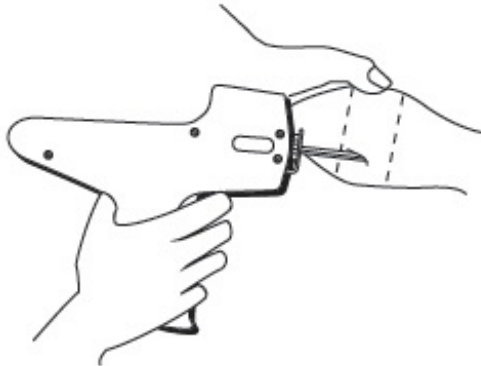


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

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.

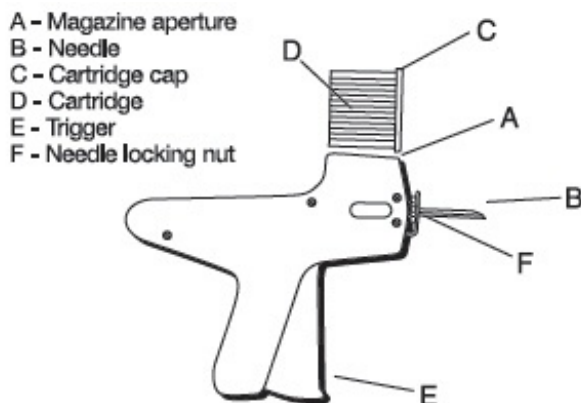


Fig. 3 - Diagram of the Implanter and Cartridge

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal 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.

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 label 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 × 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

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

Restricted Drug (California) - Use only as Directed

Rev. 03/15

MERCK

Animal Health

NADA # 141-269, Approved by FDA

US Patent # RE 39,592 E

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

152409 R1

PRINCIPAL DISPLAY PANEL - 10 x 10 Cartridge Implant Box

Revalor[®]-XS

(trenbolone acetate and estradiol)

For Steers

Fed In Confinement

For Slaughter

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

Restricted Drug (California) - use only as directed.

MERCK

Animal Health

144x107x77 mm
PSA020A04
CMK
977
x=5 y=25

Revalor-XS

(trenbolone acetate and estradiol)

**For Steers
Fed In Confinement
For Slaughter**
Box of 10 x 10 Cartridge Implants



Manufactured by a non-sterilizing process
Restricted Drug (California) - use only as directed.



LOT
EXP

Imprint area
lacquer- and color-free

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

WARNING:
Not to be used in animals for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal 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.

NADA # 141-269, Approved by FDA



Manufactured by a non-sterilizing process
Box of 10 x 10 Cartridge Implants
For Slaughter
Fed In Confinement
For Steers

(trenbolone acetate and estradiol)

Revalor-XS



150756 R1

HOW SUPPLIED:

Box of 10 x 10 implants. Contains 100 doses in ten cartridges with ten implants per cartridge. Each dose contains 10 small yellow pellets. Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol.

STORAGE CONDITIONS:

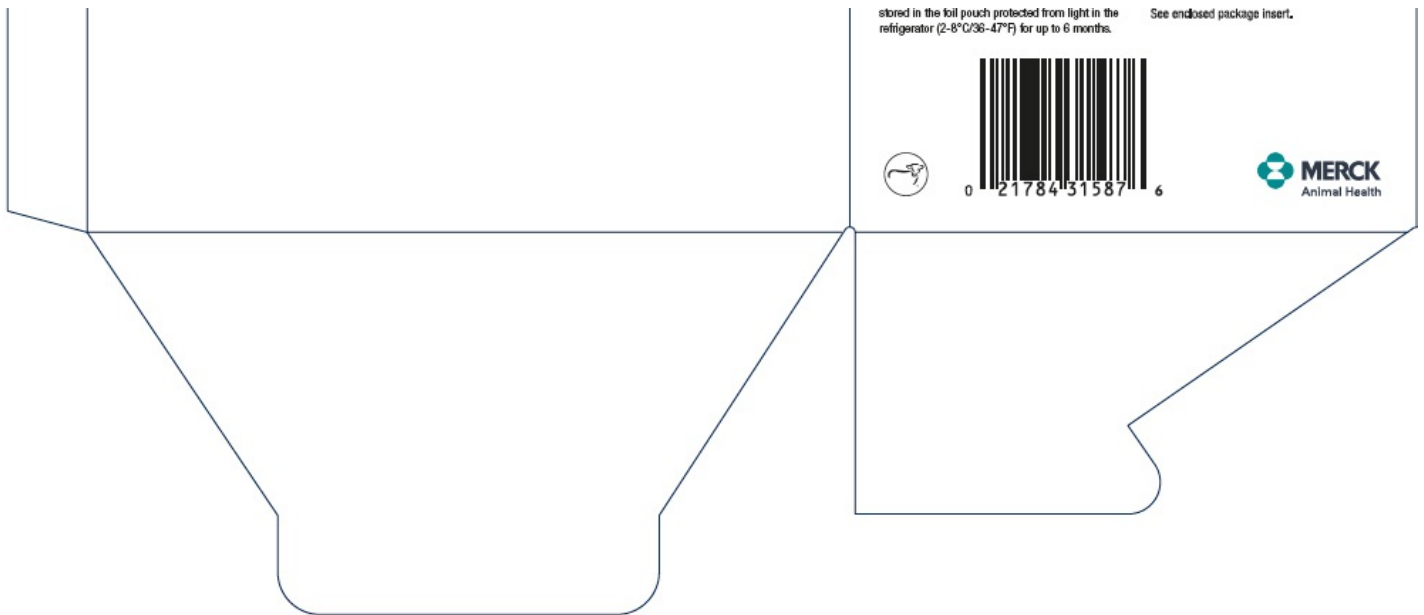
Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity. Use product before the expiration date printed on the label and on the cartridge pouch. Opened cartridges may be

INDICATIONS:

This product contains trenbolone acetate and estradiol in a slow-release delivery system which increases rate of weight gain and improves feed efficiency for up to 200 days in steers fed in confinement for slaughter.

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

USE DIRECTIONS:



REVALOR-XS

trenbolone acetate and estradiol implant

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-026
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trenbolone acetate (UNII: RUD5Y4SV0S) (trenbolone - UNII:P53R4420TR)	trenbolone acetate	200 mg
estradiol (UNII: 4TI98Z838E) (estradiol - UNII:4TI98Z838E)	estradiol	40 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-026-01	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	NADA141269	01/19/2007	

Labeler - Merck Sharp & Dohme Corp. (001317601)