

RALGRO- zeranol implant
Merck Sharp & Dohme Corp.

RALGRO® IMPLANTS FOR BEEF CATTLE

Intervet/Merck Animal Health

IMPLANTS IN CARTRIDGES for Beef Cattle

CAUTION: Do not use in bulls intended for reproduction or dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction. Edema of the vulva and udder, teat elongation, rectal and vaginal prolapse, and signs of estrus may occur when heifers are implanted. Delayed testicular development may occur in young males. To avoid difficulty in castration, young males should be castrated at the time of implanting.

Dosage: 36 mg zeranol

A single pull of the RALOGUN® trigger delivers the proper 36-mg dose (three - 12-mg pellets per chamber). Manufactured by a non-sterilizing process.

Restricted Drug (California), Use Only as Directed.

WARNING:

DO NOT ATTEMPT TO SALVAGE IMPLANT SITE FOR HUMAN OR ANIMAL FOOD. IMPLANT PELLETS IN THE EAR ONLY. ANY OTHER LOCATION IS IN VIOLATION OF FEDERAL LAW. A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.

DIRECTIONS FOR USING RALGRO® IMPLANTS IN CARTRIDGES WITH THE RALOGUN® PELLET INJECTOR

RALGRO (zeranol) is an anabolic agent that increases rate of weight gain and improves feed conversion of weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers. **RALGRO** also increases rate of weight gain of suckling beef calves. Do not use in veal calves.

Effectiveness and animal safety in veal calves have not been established. **RALGRO** pellets are stable when stored between 2° and 25°C (36° and 77°F). **RALGRO** pellets each contain 12 mg of zeranol. Three pellets are required for 36-mg dose.

STEP 1



Each chamber of the plastic RALGRO cartridge contains a full dose of RALGRO implants. Insert the cartridge in the magazine of the RALOGUN pellet injector with the hole in the axle of the cartridge pointed toward the handle of the RALOGUN pellet injector. After snapping into place, rotate cartridge clockwise to ensure proper seating, then check window at top to ensure that pellet chamber is aligned

with plunger.

STEP 2



Always use sharp needle. A dull needle tears tissue and makes proper implanting difficult. Be sure that needle is fully seated in RALOGUN pellet injector. This ensures that pellets will be expelled from the needle as RALOGUN plunger is extended. Failure to set the needle could cause the last pellet to be left in the needle and not implanted.

STEP 3



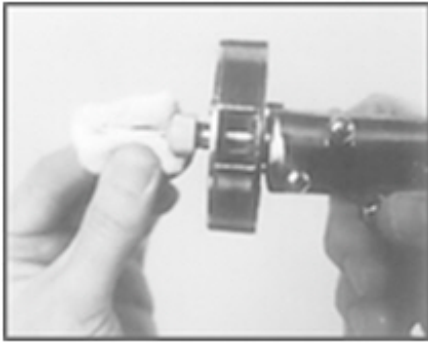
After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site.

STEP 4



The implant site 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 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. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear. Squeeze trigger of the RALOGUN pellet injector to deliver a full dose of RALGRO. Keep trigger depressed while withdrawing the needle to be sure that RALGRO implants stay in place.

STEP 5



Wipe needle with cotton or gauze moistened with alcohol or other suitable disinfectant. Do not dip needle in solution because solution clinging to inside of needle will cause plugging of needle.

STEP 6



Rotate cartridge in direction of arrow until a new dose is visible and centered in window. The RALOGUN pellet injector is now ready for next implantation.

Made in Austria

This product may not be marketed or used in the EU.

NADA #38-233, Approved by FDA.

Distributed by: Intervet Inc d/b/a Merck Animal Health, Summit, NJ 07901

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128404 R1

Presentation: 24 doses per cartridge and 10 × 10-dose strips (100 doses).

PRINCIPAL DISPLAY PANEL - 10 Cartridge Box

Contains ten 24-dose cartridges. (Dosage: 3 pellets, each containing 12 mg of Zeranol)

NDC 0061-5026-03

RALGRO®

BRAND OF ZERANOL

ANABOLIC AGENT

For increased weight gain and for improved feed conversion of weaned beef calves, growing beef cattle, feedlot steers and feedlot heifers. For increased rate of weight gain of suckling beef calves.

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

MERCK

Animal Health

Implants for Beef Cattle

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Implants for Beef Cattle
WARNING: DO NOT ATTEMPT TO SALVAGE IMPLANT SITE FOR HUMAN OR ANIMAL FOOD. IMPLANT PELLETS AS DIRECTED IN THE EAR ONLY. ANY OTHER LOCATION IS IN VIOLATION OF FEDERAL LAW.
A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.
CAUTION: DO NOT IMPLANT BULLS INTENDED FOR REPRODUCTION OR DAIRY ANIMALS WITH ZERANOL. DO NOT USE BEFORE 1 MONTH OF AGE OR AFTER WEANING IN HEIFERS INTENDED FOR REPRODUCTION.
HAZARDOUS—NOT FOR HUMAN USE.
This product may not be marketed or used in the EU.

RALGRO[®]
BRAND OF ZERANOL
ANABOLIC AGENT



**Restricted Drug (California),
Use Only as Directed.**

See package insert for use directions.
Store between 2° and 25°C (36° and 77°F).

Imprint area varnish free,
laquer free, color free
min area
50mm x 25mm

RALGRO[®]
BRAND OF ZERANOL
ANABOLIC AGENT
Implants for Beef Cattle

RALGRO[®]
BRAND OF ZERANOL
ANABOLIC AGENT

See enclosed instruction insert.
Manufactured by a non-sterilizing process.

**Restricted Drug (California),
Use Only as Directed.**

Implants for Beef Cattle

PULL TO OPEN

Contains ten 24-dose cartridges. (Dosage: 3 pellets, each containing 12 mg of Zeranol)

NDC 0061-5026-03

RALGRO[®]
BRAND OF ZERANOL
ANABOLIC AGENT

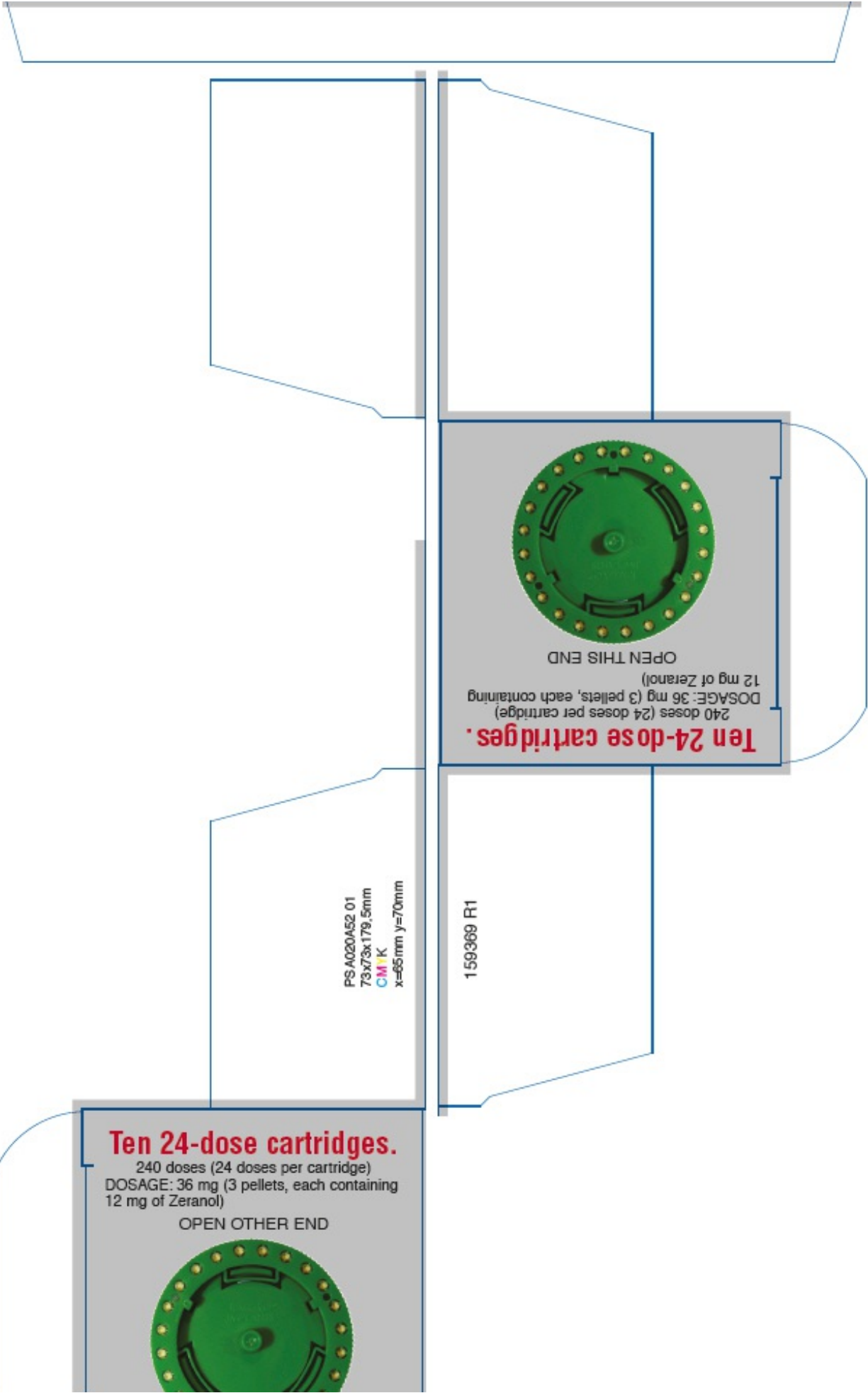
For increased weight gain and for improved feed conversion of weaned beef calves, growing beef cattle, feedlot steers and feedlot heifers. For increased rate of weight gain of suckling beef calves.
Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

BRAND OF ZERANOL
ANABOLIC AGENT



NADA #38-233, Approved by FDA.

Implants for Beef Cattle



Ten 24-dose cartridges.
240 doses (24 doses per cartridge)
DOSAGE: 36 mg (3 pellets, each containing
12 mg of Zeranol)
OPEN THIS END



PSA020A52 01
73x73x179,5mm
CMK
x=65mm y=70mm

159369 R1

Ten 24-dose cartridges.
240 doses (24 doses per cartridge)
DOSAGE: 36 mg (3 pellets, each containing
12 mg of Zeranol)
OPEN OTHER END



RALGRO

zeranol implant

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:0061-5026
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zeranol (UNII: 76LO2L2V39) (Zeranol - UNII:76LO2L2V39)	Zeranol	12 mg

Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
Magnesium Stearate (UNII: 70097M6I30)	
FD&C Yellow NO. 5 (UNII: I753WB2F1M)	
Alcohol (UNII: 3K9958V90M)	
Water (UNII: 059QF0K00R)	
Lactose Monohydrate (UNII: EWQ57Q8I5X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-5026-02	1 in 1 BOX		
2	NDC:0061-5026-03	10 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA038233	01/23/2013	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Intervet GesmbH		303380992	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Biovetra Inc		206302093	API MANUFACTURE

Revised: 9/2019

Merck Sharp & Dohme Corp.