

INTEPRITY- avilamycin granule
Elanco US Inc.

Elanco™

AF0375

BG230612X

Inteprity™

Net Weight: 25 kg (55.12 lb)

(Avilamycin Type A Medicated Article)

CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

For Use in Type C Medicated Broiler Chicken Feed Only

Do Not Use to Manufacture Type B Medicated Feed

Do not feed undiluted.

Active Drug Ingredient: Avilamycin 45.4 g per lb (100 g per kg).

Inert Ingredients: Roughage products and mineral oil.

Description:

Inteprity Type A Medicated Article is a formulation of the antibiotic avilamycin. Avilamycin is in the orthosomycin class of antibiotics.

Indication:

For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.

Feeding Directions:

Avilamycin is to be fed at 13.6 to 40.9 grams per ton of Type C medicated feed (15 to 45 ppm) as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens*.

Mixing Directions:

First, prepare an intermediate pre-blend by thoroughly mixing the required amount of Inteprity Type A medicated article in a convenient quantity of feed ingredients, and then thoroughly mix the pre-blend with non-medicated chicken feed to provide a complete Type C medicated feed containing 13.6 to 40.9 grams avilamycin per ton (15 to 45 ppm).

Starting concentration of Intepriety Type A Medicated Article	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed
grams per pound	pounds	grams per ton
45.4	0.30	13.6
	0.60	27.2
	0.90	40.9

Caution: To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. The Veterinary Feed Directive (VFD) expiration date must not exceed 90 days from the date of issuance. VFDs for avilamycin shall not be refilled.

WARNINGS:

Withdrawal Period: No withdrawal period is required.

User Safety Warnings: Avilamycin may be irritating to the eyes and may cause allergic reactions in those hypersensitive to avilamycin. Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling Intepriety Type A medicated article should use protective clothing, impervious gloves, goggles, and an approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water and seek medical attention. If wearing contact lenses, rinse the eyes first, then remove contact lenses and continue to rinse the eyes thoroughly and seek medical attention. If accidental skin contact occurs, wash all exposed areas of skin with soap and water, and seek medical attention if irritation develops. If accidental inhalation occurs, seek medical attention if breathing difficulty occurs. Not for human consumption. If accidental ingestion occurs, call a physician or poison control center. Do not induce vomiting. Keep out of reach of children. The Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a Safety Data Sheet, call 1-800-428-4441.

Adverse Drug Reactions:

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

Storage Information:

Store at less than or equal to 25°C (77°F). Excursions to 40°C (104°F) are acceptable. Avoid excessive moisture.

Not to be used after the date printed on the bag.

Restricted Drug (California) - Use Only as Directed

Approved by FDA under NADA # 141-439

Manufactured For:

Elanco US Inc. Greenfield, IN 46140

Integrity, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

TAKE TIME

OBSERVE LABEL DIRECTIONS

BG230612X

Principal Display Panel - 25 kg Bag Label

Elanco[™]

AF0375

Integrity[™]

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(Avilamycin Type A Medicated Article)

IntegrityTM

TM

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Restricted Drug (California) - Use Only as Directed

Approved by FDA under NADA # 141-438





BG230612X

Lot Number

Expiration Date

INTEGRITY

avilamycin granule

Product Information

Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:58198-0375
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
avilamycin (UNII: 720WDX56D3) (avilamycin - UNII:720WDX56D3)	avilamycin	100 g in 1 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0375-9	25 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141439	04/25/2016	

Labeler - Elanco US Inc. (966985624)

Establishment

Name	Address	ID/FEI	Business Operations
TriRx Speke Limited		228138655	API MANUFACTURE, MEDICATED ANIMAL FEED MANUFACTURE, PACK, LABEL