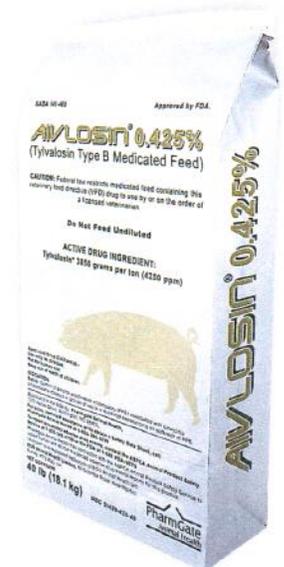


# AIVLOSIN<sup>®</sup> 0.425%

## (Tylvalosin Type B Medicated Feed)



### PRODUCT DESCRIPTION

- Antibacterial for oral administration in feed to swine.
- Each ton of product contains 3856 grams tylvalosin (4250 ppm) (1.928 g/lb).

### FORMULATION

- Free-flowing medicated feedstuff.
- Formulated for optimal dispersion, segregation, and stability in feed.
- Contains 17%-20.4% calcium.

### FDA STATUS

- Type B medicated feed for use in the manufacture of Type C medicated feeds for swine.
- Category I drug; does not require a feedmill license.
- Veterinary feed directive required: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

### INDICATION

- Swine: Control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

### DOSAGE & ADMINISTRATION

- Feed Type C medicated feed containing 38.6 grams tylvalosin/ton as the sole ration for 14 consecutive days.
- To prepare 1 ton of Type C medicated feed containing 38.6 g/ton (42.5 ppm) tylvalosin, thoroughly mix 20 pounds of AIVLOSIN<sup>®</sup> 0.425% Type B Medicated Feed with 1980 pounds of non-medicated feed.

### WITHDRAWAL PERIOD

- 0 days.
- Different withdrawal times may be required for certain export markets.

### PACKAGING

- 40-lb bags.

### STORAGE

- Store in a cool dry place at or below 77°F (25°C).

### KEY FEATURES

- Quick-acting, potent macrolide antibiotic that is not used in human health.
- Accumulates rapidly in target tissues with intracellular concentrations many times extracellular levels.<sup>1,2</sup>
- Enhances macrophage activity.<sup>1</sup>
- Easy, reliable dosing in feed for pen or whole-house control of outbreaks.
- Flexible usage; compatible with clinical or subclinical disease management programs.
- Free-flowing medicated feed facilitates consistent mixing.
- No withdrawal period (0 days).
- Wide safety margin.



14040 Industrial Road  
Omaha, NE 68144



The labeling contains complete use information, including any cautions and warnings.



**Important Safety Information:** Available under Veterinary Feed Directive only. AIVLOSIN is indicated only for the control of PPE caused by *Lawsonia intracellularis* in groups of swine in a house experiencing an outbreak of this disease. For use only in the feed of pigs. Not for use in lactating or pregnant females, or males and females intending for breeding. May cause skin irritation. People with known hypersensitivity to Tylvalosin Tartrate should avoid contact with this product. When handling Aivlosin® 0.425% Tylvalosin Type B Medicated Feed, avoid direct contact with eyes and skin. Wear a dust mask, coveralls, and impervious gloves when mixing and handling this product. Eye protection is recommended. When used in accordance with label directions, no withdrawal period is required before slaughter for human consumption.

NADA 141-460

# AIVLOSIN® 0.425%

(Tylvalosin Type B Medicated Feed)

Approved by FDA.

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

**Do Not Feed Undiluted**

**ACTIVE DRUG INGREDIENT:** Tylvalosin 3856 grams per ton (4250 ppm)

**INDICATION:**

**Swine:** Control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

**INGREDIENTS:**

Rice Hulls, Calcium Carbonate, Mineral Oil.

**MIXING DIRECTIONS:**

To prepare one ton of complete Type C medicated feed containing 38.6 grams per ton (42.5 ppm) tylvalosin, thoroughly mix 20 pounds of this medicated feed with 1980 pounds of non-medicated feed.

Pelleted or crumbled Type C medicated feeds must bear an expiration date of 1 week after the date of manufacture.

**FEEDING DIRECTIONS:** Feed the resulting Type C medicated feed containing 38.6 grams tylvalosin/ton as the sole ration for 14 consecutive days.

**CAUTION:** To assure both food safety and responsible use in swine, concurrent use of tylvalosin Type A medicated article in medicated feed and tylvalosin or another macrolide in medicated drinking water or by any other route of administration should be avoided. Not for use in swine intended for breeding. The effects of tylvalosin on swine reproductive performance, pregnancy, and lactation have not been determined. VFDs for tylvalosin shall not be refilled.

**WARNINGS:**

**WITHDRAWAL PERIOD:**

No withdrawal period is required before slaughter for human consumption.

**ANTIBACTERIAL WARNINGS:**

Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the development of drug-resistant bacteria.

**USER SAFETY WARNINGS:**

Not for use in humans. Keep out of reach of children.

May cause skin irritation. Tylvalosin has been shown to cause hypersensitivity reactions in laboratory animals. People with known hypersensitivity to tylvalosin should avoid contact with this product. In case of accidental ingestion, seek medical attention. See the Important Safety Information above and the Safety Data Sheet for additional information.

**STORAGE:** Store in a cool dry place at or below 25°C (77°F).

**NET CONTENTS:** Net weight 40 lb (18.1 kg) Bag

**For sales, technical assistance or to obtain a Safety Data Sheet, call Pharmgate Animal Health at 1-800-380-6099**

**To report suspected adverse drug events, contact the ASPCA Animal Product Safety Service at 1-800-345-4735 or the FDA at 1-888-FDA-VETS**

Pharmgate Animal Health has contracted with the ASPCA Animal Product Safety Service to collect human and animal suspected adverse drug events reports for this product.



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800.832.8303 www.pharmgateAH.com  
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