AIVLOSIN® 17%

(Tylvalosin Type A Medicated Article)

Product Description

- Antibacterial for oral administration in feed to swine.
- Each pound of product contains tylvalosin 17% w/w, a macrolide antibiotic.

Formulation

- Free-flowing granules.
- Formulated for optimal dispersion, segregation, and stability in feed.

FDA Status

- Type A Medicated Article for use in the manufacture of Type B or 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 manufacture 1 ton of Type C medicated feed containing 38.6 g/ton (42.5 ppm) tylvalosin, mix 0.5 pound of AIVLOSIN® 17% Type A Medicated Article with 1999.5 pounds of non-medicated feed.

Withdrawal Period

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

Packaging

- 50-lb bags.

Storage

- Store in a cool dry place at or below 77ºF (25ºC).

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.[1,2]
- Enhances macrophage activity.[1]
- 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 granular formulation facilitates consistent mixing.
- No withdrawal period (0 days).
- Wide safety margin.

PharmGate Animal Health
14040 Industrial Road
Omaha, NE 68144
800.832.8303
www.pharmgateAH.com

The labeling contains complete use information, including any cautions and warnings. Always read, understand and follow the labeling and use directions. See the reverse side for use directions and additional information.

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® 17% Tylvalosin Type A Medicated Article, 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 pe riod is required before slaughter for human consumption.

NADA 141-460 **Approved by FDA.**

AIVLOSIN® 17%

(Tylvalosin 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

Do Not Feed Undiluted – For Further Manufacturing Only – For Use in Swine Feed Only

ACTIVE DRUG INGREDIENT: Tylvalosin 17% w/w (77.12 g tylvalosin/lb, equivalent to tylvalosin tartrate 19.4% w/w)

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

DIRECTIONS FOR USE:

MIXING DIRECTIONS:

Swine:

Control of Porcine Proliferative Enteropathy

Preparation of Type B medicated feed containing 3.856 grams per ton (4.250 ppm) tylvalosin:

Prepare tylvalosin Type B medicated feed in mash form only.

To manufacture one ton of Type B medicated feed containing 3,856 g/ton (4,250 ppm) tylvalosin, mix 50 pounds of Aivlosin® 17% Type A Medicated Article with 1950 pounds of non-medicated feed.

Preparation of Type C medicated feed containing 38.6 grams per ton (42.5 ppm) tylvalosin:

To manufacture one ton of Type C medicated feed containing 38.6 g/ton (42.5 ppm) tylvalosin, mix 0.5 pound of Aivlosin® 17% Type A Medicated Article with 1999.5 pounds of non-medicated feed.

To aid in the even distribution of drug in the finished feed, add the full amount of Aivlosin® 17% Type A Medicated Article into a small portion of the feed and mix. Blend this mixture into the remainder of the feed and mix thoroughly. Pelleted or crumbled Type C medicated feeds must bear an expiration date of 1 week after the date of manufacture.

FEEDING DIRECTIONS: Feed 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 or inhalation, seek medical attention. When handling Aivlosin® 17% Type A Medicated Article and preparing medicated feeds, avoid direct contact with the eyes and skin. Wear a dust mask, coveralls and impervious gloves when mixing and handling this product. Eye protection is recommended. In case of accidental eye exposure, wash eyes immediately with water and seek medical attention. If wearing contact lenses, immediately rinse the eyes first, then remove contact lenses and continue to rinse the eyes thoroughly and seek medical attention.

In case of accidental skin exposure, wash contaminated skin thoroughly.

The Safety Data Sheet contains more detailed occupational safety information.

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

NET CONTENTS: 50 lb (22.7 kg).50 lb (22.7 kg) **Use only as directed.**

Distributed in the USA by: **Pharmgate Animal Health**, 1015 Ashes Drive, Wilmington, NC 28405.

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.

1. Stuart et al. *Pig J* 2007; 60:26-35.
2. Data on file. ECO Animal Health.

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