Product Profile

AIVLOSIN®

Water Soluble Granules

(62.5% w/w Tylvalosin as Tylvalosin Tartrate)

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Water Soluble Granules

Product Description

- **Water-soluble antibiotic for oral use by administration in the drinking water**
- **Contains 62.5% w/w tylvalosin (as tylvalosin tartrate), a novel macrolide antibiotic**
- **Veterinary prescription; for use in drinking water of swine**

Formulation

- Water-soluble granules; suitable for both drinking water and stock solutions.

Indication

- Control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,* and *Streptococcus suis* in groups of swine in buildings experiencing an outbreak of SRD.
- Control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* in groups of swine in buildings experiencing an outbreak of PPE.

Packaging

- Cartons containing either 10 x 160-g or 5 x 400-g sachets.

Dosage / Administration

- May be mixed directly into the drinking water system or first mixed as a stock solution (e.g., for automatic water proportioners).
- Prepare a fresh batch of medicated stock solution or medicated drinking water daily.
- Prepare drinking water medicated with 50 ppm tylvalosin daily. Administer continuously for 5 consecutive days.
- Based on a theoretical daily water consumption rate of 10% of body weight, 50 ppm tylvalosin in drinking water provides the target dose rate of 5 mg tylvalosin/kg body weight per day.

Precautions

- **Do not mix or administer medicated water using equipment made of galvanized metal.** Galvanized metal adversely affects the stability of tylvalosin in water and may reduce the effectiveness of the product.
- **Not for use in breeding animals.** The effects of tylvalosin on swine reproductive performance, pregnancy and lactation have not been determined.

Withdrawal Period

- 0-days (no withdrawal needed).

Key Features

- **Dual efficacy against both respiratory (SRD) and enteric (PPE) pathogens.**
- **Quick-acting, potent macrolide antibiotic that is not used in human health.**
- **Supports judicious, responsible antibiotic use.**
- **Wide safety margin; compatible when treating pigs with ionophores.**
- **Enters into white blood cells within two hours (*in vitro*).[1]**
- **Accumulates rapidly in lung and small intestinal tissue after treatment.[2]**
- **No withdrawal period (0 days).**
- **Easy, reliable dosing in drinking water for rapid control of new outbreaks.**
- **Palatable, non-clogging formulation.**

Storage

- Store at or below 25°C (77°F).
- 2-year shelf-life for unopened sachets.

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.

Pharmgate ANIMAL HEALTH

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Important Safety Information: Available under prescription only. AIVLOSIN is indicated for the control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida* and *Streptococcus suis*, or porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis*, in groups of swine in buildings experiencing an outbreak of either disease. For use only in drinking water of pigs. Not for use in lactating or pregnant females, or males and females intended for breeding. People with known hypersensitivity to tylvalosin tartrate should avoid contact with this product. When used in accordance with label directions, no withdrawal period is required before slaughter for human consumption.

NADA 141-336 **Approved by FDA.**

AIVLOSIN®

(62.5% w/w Tylvalosin as Tylvalosin Tartrate)

Water Soluble Granules

Use only as directed.
For use only in the drinking water of pigs.
Not for use in lactating or pregnant females, or males and females intended for breeding.

CAUTION:
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PRODUCT DESCRIPTION:
Aivlosin® (tylvalosin tartrate) Water Soluble Granules is a water soluble granular powder for oral use by administration in the drinking water.

ANTIBIOTIC CLASSIFICATION:
Tylvalosin, the active ingredient in Aivlosin® Water Soluble Granules, is a macrolide antibiotic.

INDICATIONS:
For Swine:
Control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.
Control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,* and *Streptococcus suis* in groups of swine in buildings experiencing an outbreak of SRD.

DOSAGE AND ADMINISTRATION:
Prepare drinking water medicated with 50 parts per million tylvalosin. Administer continuously in drinking water for five (5) consecutive days. Galvanized metal adversely affects the stability of tylvalosin in water and may reduce the effectiveness of the product. Prepare a fresh batch of medicated stock solution or medicated drinking water daily.

MIXING DIRECTIONS:
Direct Mixing:
When mixing the product directly into the drinking water system, the contents of the sachet should be sprinkled onto the surface of the water and mixed slowly and thoroughly for at least 3 minutes. Prepare a fresh batch of medicated drinking water daily.

Stock Solution:
When preparing a stock solution, the recommended concentration is one 40-gram sachet per US gallon, or one 160-g sachet per four (4) US gallons or one 400-gram sachet per 10 US gallons. Sprinkle sachet contents onto the surface of the water of the stock solution and mix slowly and thoroughly for at least 10 minutes. Use the stock solution for dilution into the drinking water system as soon as it is prepared. Add one (1) fluid ounce of this stock solution per 131 fluid ounces (1 US gallon, 3 fluid ounces) of drinking water to provide a final concentration of 50 ppm. If using an automatic water proportioner, set the flow rate to add stock solution at a rate of 1 fluid ounce per 131 fluid ounces of drinking water (1:131). Prepare a fresh batch of medicated stock solution daily.

WARNINGS:

WITHDRAWAL PERIOD:
When used in accordance with label directions, 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 pathogenic bacteria.

USER SAFETY WARNINGS:
NOT FOR USE IN HUMANS.
KEEP OUT OF REACH OF CHILDREN.
May cause skin irritation. Tylvalosin tartrate has been shown to cause hypersensitivity reactions in laboratory animals.
People with known hypersensitivity to tylvalosin tartrate should avoid contact with this product. In case of accidental ingestion, seek medical advice.
When handling Aivlosin® Water Soluble Granules and preparing medicated drinking water, avoid direct contact with the eyes and skin.
The Safety Data Sheet contains more detailed occupational safety information.

PRECAUTIONS:
Not for use in lactating or pregnant females, or males and females intended for breeding.
The effects of tylvalosin on swine reproductive performance, pregnancy, and lactation have not been determined.

ADVERSE REACTIONS IN ANIMALS:
No adverse reactions related to the drug were observed during clinical or target animal safety trials. To report suspected adverse reactions in animals, contact the ASPCA Animal Product Safety Service at 1-800-345-4735 or the FDA at 1-888-FDA-VETS.

EFFECTIVENESS: Swine:
Control of Porcine Proliferative Enteropathy (PPE):
A multi-location challenge model study was conducted to confirm the effectiveness of Aivlosin® Water Soluble Granules for the control of PPE associated with *Lawsonia intracellularis*. Pigs were challenged by intragastric gavage with a mucosal homogenate containing a North American isolate of *Lawsonia intracellularis* isolated in 2005 that induces representative disease in challenged pigs. When at least 15% of the study pigs were showing signs of infection based on abnormal fecal scores, pigs were provided water containing tylvalosin at an inclusion rate of 50 ppm for five consecutive days, or were provided non-medicated water. Effectiveness was evaluated using clinical scores (pig demeanor score, abdominal appearance score, and fecal score) and clinically-validated gross PPE lesion scores. A conclusion of the effectiveness of 50 ppm tylvalosin for the control of PPE was determined based on a statistically significant ($p = 0.0103$) improvement in the clinically-validated gross PPE lesion scores in the 50 ppm tylvalosin-treated group compared to the non-medicated group.

Control of Swine Respiratory Disease (SRD):
The effectiveness of Aivlosin® Water Soluble Granules for the control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida* and *Streptococcus suis* was investigated in a natural field infection study conducted in the United States (three study sites) and Canada (one study site). Day 0 was defined when at least 15% of the candidate pigs were deemed clinically affected with SRD (moderate or severe respiratory score, moderate or severe depression score, and rectal temperature greater than or equal to 104.0 °F). On Day 0 a total of 980 pigs were enrolled and randomly assigned to a tylvalosin-treated group (50 ppm tylvalosin in drinking water for 5 consecutive days) or a non-medicated control group. Treatment success was evaluated on Day 7 and was defined as a pig with normal or mild respiratory score, normal or mild depression score, and rectal temperature less than 104.0 °F. The proportion of pigs meeting the definition of treatment success was numerically higher in the tylvalosin-treated group (48.5%) compared to the proportion of pigs meeting the definition of treatment success in the non-medicated control group (41.6%), and the observed difference was statistically significant (p=0.0353).

ANIMAL SAFETY: Swine:
Margin of safety: Aivlosin® Water Soluble Granules given orally in drinking water at 0, 50, 150 and 250 ppm tylvalosin (0, 1X, 3X and 5X the labeled dose, respectively) to 8 healthy pigs per treatment group over 15 days (3X the labeled duration) did not result in drug-induced clinical signs, gross pathologic lesions, histopathologic lesions or clinically-relevant clinical pathology abnormalities.

For 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 FDA at 1-888-FDA-VETS.

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

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