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. Each gram of Aivlosin® Water Soluble Granules contains 0.625 grams of tylvalosin as tylvalosin tartrate.

TYLVALOSIN TARTRATE CHEMICAL NOMENCLATURE AND STRUCTURE:

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

INDICATIONS:
Swine:
Control of porcine proliferative enteropathy (PPE) associated with Lawsonia intracellularis infection in groups of swine in buildings (PPE) associated with control of porcine proliferative enteropathy.

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

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:
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. 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. If irritation persists, seek medical attention.

Avoid eating, chewing gum and smoking during handling.

The Material Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or obtain a Material Safety Data Sheet, call the ASPCA Animal Product Safety Service at 1-800-345-4735.

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. The safety and efficacy of this formulation in other species other than swine 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.

CLINICAL PHARMACOLOGY:
Tylvalosin is a 16-membered semi-synthetic macrolide antibiotic. Macrolides are generally considered to be bacteriostatic agents that exert their antibiotic effect by reversibly binding to the 23S rRNA of the 50S ribosomal subunit, thereby inhibiting bacterial protein synthesis. The spectrum of activity of most available macrolides used in veterinary medicine is primarily against Gram-positive bacteria and Mycoplasmas, with some activity against Gram-negative fastidious bacteria. These compounds have no activity against the naturally resistant Enterobacteriaceae including Escherichia coli and Salmonella spp.

Typically, macrolides achieve higher concentrations in tissues than in plasma.

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. 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.

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.

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

HOW SUPPLIED:
Aivlosin® Water Soluble Granules is packaged in 40-, 160- and 400-gram sachets supplied in boxes holding 20, 10 and 5 sachets respectively.

LOT NO.:
Printed on label.
EXPIRY:
Printed on label.

Distributed in the USA by:

For technical assistance or to obtain a Material 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.

Aivlosin® is a registered trademark of ECO Animal Health Ltd.
©2012 Pharmgate Animal Health Inc.