Product Profile

AIVLOSIN®

Water Soluble Granules
(62.5% w/w Tylvalosin as Tylvalosin Tartrate)

AIVLOSIN®
(62.5% w/w Tylvalosin as Tylvalosin Tartrate)
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
- Treatment of Porcine Proliferative Enteropathy (PPE) associated with *Lawsonia intracellularis* in pigs.
- Aid in reducing the severity of Swine Respiratory Disease (SRD) associated with *Haemophilus parasuis, Pasteurella multocida, Streptococcus suis* and *Mycoplasma hyopneumoniae* in groups of pigs experiencing an outbreak of SRD.

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 10-20% body weight, 50 ppm tylvalosin in drinking water will provide a dose rate of 5-10 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
- 24 hour withrdrawal period.

Key Features

- **Quick-acting, potent macrolide antibiotic that is not used in human health.**
- **Broadest label indication for SRD, including aiding in the reduction of *Mycoplasma hyopneumoniae*.**
- **Accumulates rapidly in lung and small intestinal tissue after treatment.[1]**
- **Enters into white blood cells within two hours (*in vitro*).[2]**
- **24 hour withdrawal period.**
- **Wide safety margin; compatible when treating pigs with ionophores.**
- **Palatable, non-clogging formulation.**
- **Supports responsible use of antibiotics through fewer milligrams of antibiotic per use per pig.**

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

1800 Sir Tyler Drive
Wilmington, NC 28405
1 (800) 380-6099
Pharmgate.com

DIN 02373505

Veterinary Use Only/ Usage vétérinaire seulement

AIVLOSIN®

Water Soluble Granules

62.5% w/w tylvalosin (as tylvalosin tartrate)
62,5 % p/p de tylvalosine (sous forme de tartrate de tylvalosine)

DESCRIPTION:
Aivlosin® Water Soluble Granules is a water soluble granular powder containing 62.5% w/w tylvalosin (as tylvalosin tartrate) 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 the treatment of Porcine Proliferative Enteropathy (PPE) associated with *Lawsonia intracellularis* in pigs. As an aid in reducing the severity of Swine Respiratory Disease (SRD) associated with *Haemophilus parasuis, Pasteurella multocida, Streptococcus suis* and *Mycoplasma hyopneumoniae* in groups of pigs experiencing an outbreak of SRD.
TARGET SPECIES: Pig
DOSAGE AND ADMINISTRATION:
To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently.
For use in drinking water of swine only.

Aivlosin® Water Soluble Granules sachet size	**160 g**	**400 g**
Tylvalosin content of sachet (grams)	100	250
Volume of drinking water (L)	2000	5000
Volume of drinking water (US gallons)	528	1320
Tylvalosin inclusion rate in water	50 parts per million (ppm)	

Note: Based on theoretical daily water consumption rate of 10-20% body weight, 50 ppm tylvalosin in drinking water will provide a dose rate of 5-10 mg tylvalosin/kg body weight per day.

Administer continuously in drinking water. Medicated water should be the only source of drinking water during the treatment period. If improvement is not observed within 5 days, the diagnosis should be reconfirmed.
MIXING:
Keep water supply equipment clean and in good operating condition. Clean water medication equipment before and after each use. Only a sufficient amount of medicated drinking water should be prepared to cover daily requirements. 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. Prepare a fresh batch of medicated stock solution or medicated drinking water daily. Aivlosin® Water Soluble Granules may be mixed directly into the drinking water system or first mixed as a stock solution in a smaller amount of water, which is then added to the drinking water system, for example, using an automatic water proportioner.
Direct Mixing:
Prepare a fresh batch of medicated drinking water daily. 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 until a clear solution is produced (usually within 3 minutes).
Stock Solution:
Prepare a fresh batch of medicated stock solution daily. When preparing a stock solution for an automatic water proportioner, the recommended maximum concentration is one-160 g sachet per 16 L (~4 US gallons) or one-400 g sachet per 40 L (~10 US gallons). Sprinkle contents onto the surface of the water and mix slowing and thoroughly for 10 minutes. After this time, any remaining cloudiness will not affect tylvalosin concentration. Use the stock solution for dilution into the drinking water system as soon as it is prepared. Add 32 mL of this stock solution per 4 L drinking water to provide a final concentration of 50 ppm. Prepare drinking water medicated with 50 parts per million tylvalosin.

Administer continuously in the drinking water for five (5) consecutive days. Based on a theoretical daily water consumption rate of 10-20% body weight, 50 ppm tylvalosin in drinking water will provide a dose rate of 5-10 mg tylvalosin/kg body weight per day.
CAUTIONS:
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.
Note: Good management and hygiene practices should be followed to reduce the risk of re-infection.
WARNINGS:
Treated swine must not be slaughtered for use in food for at least 24 hours after the latest treatment with this drug. Tylvalosin has been shown to cause hypersensitivity reactions in laboratory animals; therefore, people with known hypersensitivity to tylvalosin tartrate should avoid contact with this product. When mixing Aivlosin® Water Soluble Granules and handling the medicated water, avoid inhalation, oral exposure and direct contact with skin or eyes. Keep out of reach of children.
ADVERSE REACTIONS:
No adverse reactions related to the drug were observed during clinical or target animal safety trials.
CLINICAL PHARMACOLOGY AND MICROBIOLOGY:
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 Enterbacteriaceae including Escherichia coli and Salmonella spp. Minimal inhibitory concentration (MIC) data for *Lawsonia intracellularis* have been generated with the intracellular MIC value of 32 µg/mL for three tested strains (McOrist, 2012; Gebhart, 2000) and MIC of >64 µg/mL for another strain (Gebhart, 2000). All isolates of *Bordetella bronchiseptica* (n=38) from the pilot effectiveness study conducted in the USA in 2013 showed tylvalosin MIC values of >256 µg/mL. 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. Typically macrolides achieve higher concentrations in tissues than in plasma.
EFFECTIVENESS:
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 with 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, Streptococcus suis* and *Mycoplasma hyopneumoniae* 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 104.0oF). 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 104.0oF. 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 group (41.6%), and the observed difference was statistically significant (p=0.0353).

To confirm the presence of *M. hyopneumoniae*, lung samples from pigs in the field study were screened with a quantitative polymerase chain reaction (qPCR) test and microbiological culture. Of the 976 samples tested, 185 (19%) were qPCR positive and 9 cultures were positive for *M. hyopneumoniae*. The data from both the multicentric field study and the experimentally-induced infection model study described below demonstrates that tylvalosin is effective as an aid in reducing the severity of SRD associated with *M. hyopneumoniae*.

Additional data to demonstrate the effectiveness of Aivlosin® Water Soluble Granules for the control of SRD associated with *Mycoplasma hyopneumoniae* was obtained in an experimentally-induced infection model study. Two hundred and forty (240) commercial crossbred pigs were challenged endotracheally with a representative isolate of *M. hyopneumoniae*. One hundred and ninety-two (192) study pigs were randomly assigned to either a tylvalosin-treated group (50 ppm tylvalosin in drinking water for 5 consecutive days) or a non-medicated control group. Treatment was started when at least four of eight randomly pre-selected sentinel pigs exhibited a minimum of 3% weighted gross lung lesions consistent with *M. hyopneumoniae* infection. After a 5-day treatment period and a 5-day post-treatment period, study pigs were euthanized and necropsy performed to determine lung lesion scores. The analysis included 95 tylvalosin-treated pigs and 93 non-medicated control pigs. There was a statistically significant (p<0.0001) improvement in pen mean *M. hyopneumoniae* lung lesion scores in the 50 ppm tylvalosin-treated pigs (5.1%) compared to negative control (10.9%).
ANIMAL SAFETY:
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 labelled dose, respectively) to 8 healthy pigs per treatment group over 15 days (3X the labelled duration) did not result in drug-induced clinical signs, gross pathologic lesions, histopathologic lesions or clinically-relevant clinical pathology abnormalities.
STORAGE:
Store at or below 25ºC.
HOW SUPPLIED:
Aivlosin® Water Soluble Granules is packaged in cartons containing 10 x 160 g or 5 x 400 g sachets.

ECO Animal Health Limited
78 Coombe Road, New Malden, Surrey, KT3 4QS UK

Distributed in Canada by
Pharmgate Animal Health Canada Inc.
5204 Tenth Line, R. R. #2 Erin, ON N0B 1T**0**

For technical service and SDS, call: 1 800 465 2450
To report adverse events, call: 1 833 531 0114

Pharmgate ANIMAL HEALTH

Aivlosin® is a registered trademark of ECO Animal Health Ltd.
Date on which package leaflet was approved: January 8, 2021

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

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Profil du produit

AIVLOSIN[MD]

Granules hydrosolubles

(62,5 % p/p tylvalosine sous forme de tartrate de tylvalosine)

AIVLOSIN®
(62.5% w/w Tylvalosin as Tylvalosin Tartrate)
Water Soluble Granules

Description du produit

- **Antibiotique hydrosoluble pour usage oral pour administration dans l'eau d'abreuvement**
- **Contient 62,5 % p/p de tylvalosine (sous forme de tartrate de tylvalosine), un nouvel antibiotique macrolide**
- **Prescription vétérinaire; pour usage dans l'eau d'abreuvement des porcs**

Formule

- Granules hydrosolubles; convenant à l'eau d'abreuvement et aux solutions-mères.

Indication

- Pour le traitement de l'entéropathie proliférative porcine (EPP) associée à *Lawsonia intracellularis* chez les porcs.
- Aide à réduire la gravité de la maladie respiratoire des porcs (MRP) associée à *Haemophilus parasuis*, *Pasteurella multocida, Streptococcus suis* et *Mycoplasma hyopneumoniae* dans les troupeaux de porcs atteints d'une crise de MRP.

Présentation

- Boîtes contenant soit 10 sachets de 160 g ou 5 sachets de 400 g.

Dosage et administration

- Peut être mélangé directement dans le système d'eau d'abreuvement ou au préalable sous forme de solution-mère (par ex., pour les doseurs d'eau automatiques).
- Préparez un nouveau lot de solution-mère médicamenteuse ou d'eau d'abreuvement médicamenteuse chaque jour.
- Préparez l'eau d'abreuvement médicamenteuse avec 50 ppm de tylvalosine quotidiennement. Administrez de manière continue pendant cinq jours consécutifs.
- Basé sur un taux de consommation quotidien théorique d'eau de 10 % du poids, 50 ppm de tylvalosine dans l'eau d'abreuvement fournit une dose cible de 5 à 10 mg de tylvalosine/kg de poids par jour.

Précautions

- **Ne pas mélanger et ne pas administrer l'eau médicamenteuse au moyen d'un équipement fait de métal galvanisé.** Le métal galvanisé nuit à la stabilité de la tylvalosine dans l'eau et peut réduire l'efficacité du produit.
- **Ne pas administrer aux animaux reproducteurs.** Les effets de la tylvalosine sur la performance de la reproduction, la gestation et la lactation n'ont pas été déterminés.

Période de retrait

- Période de retrait de 24 heures.

Principales caractéristiques

- **Nouvel antibiotique macrolide puissant à action rapide qui n'est pas utilisé pour les humains.**
- **Plus vaste indication sur l'étiquette pour la MRP, y compris faciliter la réduction de la *Mycoplasma hyopneumoniae*.**
- **S'accumule rapidement dans le poumon et l'intestin grêle suite au traitement.[1]**
- **Pénètre dans les globules blancs dans un délai de deux heures (in vitro).[2]**
- **Période de retrait de 24 heures.**
- **Grande marge de sécurité; compatible au traitement des porcs avec des ionophores.**
- **Formule appétissante ne créant pas de colmatage.**
- **Facilite l'usage responsable des antibiotiques en réduisant le nombre de milligrammes d'antibiotique utilisés par dose par porc.**

Entreposage

- Entreposer à une température inférieure à 25 °C (77 °F).
- Durée de conservation de deux ans pour les sachets non ouverts.

L'étiquette comprend tous les renseignements sur l'utilisation, y compris les mises en garde et les avertissements.
Lisez, comprenez et suivez toujours les directives et le mode d'emploi se trouvant sur l'étiquette.
Consultez le verso pour le mode d'emploi et des renseignements supplémentaires.

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AIVLOSIN®

Water Soluble Granules

62.5% w/w tylvalosin (as tylvalosin tartrate)
62,5 % p/p de tylvalosine (sous forme de tartrate de tylvalosine)

DESCRIPTION:
Aivlosin® Water Soluble Granules is a water soluble granular powder containing 62.5% w/w tylvalosin (as tylvalosin tartrate) 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:
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TARGET SPECIES: Pig
DOSAGE AND ADMINISTRATION:
To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently.
For use in drinking water of swine only.

Aivlosin® Water Soluble Granules sachet size	**160 g**	**400 g**
Tylvalosin content of sachet (grams)	100	250
Volume of drinking water (L)	2000	5000
Volume of drinking water (US gallons)	528	1320
Tylvalosin inclusion rate in water	50 parts per million (ppm)	

Note: Based on theoretical daily water consumption rate of 10-20% body weight, 50 ppm tylvalosin in drinking water will provide a dose rate of 5-10 mg tylvalosin/kg body weight per day.

Administer continuously in drinking water. Medicated water should be the only source of drinking water during the treatment period. If improvement is not observed within 5 days, the diagnosis should be reconfirmed.
MIXING:
Keep water supply equipment clean and in good operating condition. Clean water medication equipment before and after each use. Only a sufficient amount of medicated drinking water should be prepared to cover daily requirements. 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. Prepare a fresh batch of medicated stock solution or medicated drinking water daily. Aivlosin® Water Soluble Granules may be mixed directly into the drinking water system or first mixed as a stock solution in a smaller amount of water, which is then added to the drinking water system, for example, using an automatic water proportioner.
Direct Mixing:
Prepare a fresh batch of medicated drinking water daily. 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 until a clear solution is produced (usually within 3 minutes).
Stock Solution:
Prepare a fresh batch of medicated stock solution daily. When preparing a stock solution for an automatic water proportioner, the recommended maximum concentration is one-160 g sachet per 16 L (~4 US gallons) or one-400 g sachet per 40 L (~10 US gallons). Sprinkle contents onto the surface of the water and mix slowing and thoroughly for 10 minutes. After this time, any remaining cloudiness will not affect tylvalosin concentration. Use the stock solution for dilution into the drinking water system as soon as it is prepared. Add 32 mL of this stock solution per 4 L drinking water to provide a final concentration of 50 ppm. Prepare drinking water medicated with 50 parts per million tylvalosin.

Administer continuously in the drinking water for five (5) consecutive days. Based on a theoretical daily water consumption rate of 10-20% body weight, 50 ppm tylvalosin in drinking water will provide a dose rate of 5-10 mg tylvalosin/kg body weight per day.
CAUTIONS:
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.
Note: Good management and hygiene practices should be followed to reduce the risk of re-infection.
WARNINGS:
Treated swine must not be slaughtered for use in food for at least 24 hours after the latest treatment with this drug. Tylvalosin has been shown to cause hypersensitivity reactions in laboratory animals; therefore, people with known hypersensitivity to tylvalosin tartrate should avoid contact with this product. When mixing Aivlosin® Water Soluble Granules and handling the medicated water, avoid inhalation, oral exposure and direct contact with skin or eyes. Keep out of reach of children.
ADVERSE REACTIONS:
No adverse reactions related to the drug were observed during clinical or target animal safety trials.
CLINICAL PHARMACOLOGY AND MICROBIOLOGY:
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 Enterbacteriaceae including Escherichia coli and Salmonella spp. Minimal inhibitory concentration (MIC) data for *Lawsonia intracellularis* have been generated with the intracellular MIC value of 32 µg/mL for three tested strains (McOrist, 2012; Gebhart, 2000) and MIC of >64 µg/mL for another strain (Gebhart, 2000). All isolates of *Bordetella bronchiseptica* (n=38) from the pilot effectiveness study conducted in the USA in 2013 showed tylvalosin MIC values of >256 µg/mL. 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. Typically macrolides achieve higher concentrations in tissues than in plasma.
EFFECTIVENESS:
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 with 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, Streptococcus suis* and *Mycoplasma hyopneumoniae* 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 104.0oF). 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 104.0oF. 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 group (41.6%), and the observed difference was statistically significant (p=0.0353).

To confirm the presence of *M. hyopneumoniae*, lung samples from pigs in the field study were screened with a quantitative polymerase chain reaction (qPCR) test and microbiological culture. Of the 976 samples tested, 185 (19%) were qPCR positive and 9 cultures were positive for *M. hyopneumoniae*. The data from both the multicentric field study and the experimentally-induced infection model study described below demonstrates that tylvalosin is effective as an aid in reducing the severity of SRD associated with *M. hyopneumoniae*.

Additional data to demonstrate the effectiveness of Aivlosin® Water Soluble Granules for the control of SRD associated with *Mycoplasma hyopneumoniae* was obtained in an experimentally-induced infection model study. Two hundred and forty (240) commercial crossbred pigs were challenged endotracheally with a representative isolate of *M. hyopneumoniae*. One hundred and ninety-two (192) study pigs were randomly assigned to either a tylvalosin-treated group (50 ppm tylvalosin in drinking water for 5 consecutive days) or a non-medicated control group. Treatment was started when at least four of eight randomly pre-selected sentinel pigs exhibited a minimum of 3% weighted gross lung lesions consistent with *M. hyopneumoniae* infection. After a 5-day treatment period and a 5-day post-treatment period, study pigs were euthanized and necropsy performed to determine lung lesion scores. The analysis included 95 tylvalosin-treated pigs and 93 non-medicated control pigs. There was a statistically significant (p<0.0001) improvement in pen mean *M. hyopneumoniae* lung lesion scores in the 50 ppm tylvalosin-treated pigs (5.1%) compared to negative control (10.9%).
ANIMAL SAFETY:
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 labelled dose, respectively) to 8 healthy pigs per treatment group over 15 days (3X the labelled duration) did not result in drug-induced clinical signs, gross pathologic lesions, histopathologic lesions or clinically-relevant clinical pathology abnormalities.
STORAGE:
Store at or below 25°C.
HOW SUPPLIED:
Aivlosin® Water Soluble Granules is packaged in cartons containing 10 x 160 g or 5 x 400 g sachets.

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78 Coombe Road, New Malden, Surrey, KT3 4QS UK

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Date on which package leaflet was approved: January 8, 2021

1. Données internes. ECO Animal Health.
2. Stuart et al. Pig J 2007; 60:26- 35.

Aivlosin[MD] est une marque déposée de ECO Animal Health; Ltd., Londres, RU.

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