

NADA 141-336

Approved by FDA.

AIVLOSIN[®]

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

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.

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

Read Product Information provided in the package insert carefully for complete details.

DOSAGE AND ADMINISTRATION:

Swine: Control of Porcine Proliferative Enteropathy

Prepare drinking water containing 50 parts per million Tylvalosin. Add Aivlosin[®] Water Soluble Granules to drinking water as illustrated in the following table.

Aivlosin [®] Water Soluble Granules sachet size	160 grams
Tylvalosin content of sachet (grams)	100
Recommended volume of stock solution (US gallons)	4
Volume of drinking water (US gallons)	528
Final tylvalosin inclusion rate in drinking water	50 parts per million (ppm)

Administer continuously in drinking water for five (5) consecutive days.

Keep water supply equipment clean and in good operating condition. Clean water medication equipment before and after each use. Do not mix or administer Tylvalosin 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.

MIXING DIRECTIONS: See Product Information provided in the package insert for details.

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.

Net contents: 160 grams

Aivlosin[®] Water Soluble Granules

NDC 51429-160-10



LOT NO. / EXP:

'AREA FOR LOT & EXP'

Eco Animal Health

160g Sachet Carton

VIEW AS PRINT

160g Sachet Carton:

Die Line: 1538l

A/B/H: 250 x 185 x 155mm

Board: As previous 160g carton

Style: Crashlock with Double Base

Date: 25/05/11

1 Box Holds 10 Sachets (1.86 kg)

Please Note: Die Line Does Not Print

OUTER DIE LINE SHOWS CUTTING DIE ONLY & DOES NOT PRINT
THIS COLOUR PROOF IS NOT ACCURATE FOR COLOUR

Artwork: Aivosin 160g Sachet Carton Pigs - USA Colours: PMS 1807 PMS 871 BLACK VFA CUTTER		Code Number: US06SC-1 Size: 250 x 185 x 155mm Date: 23-10-12 Print Process: LITHO
Sign off: Packaging: P. Parmenter ✓ Date: 00-11-12 Regulatory: R. Dodemaide ✓ Date: 00-11-12 Operations: S. Long ✓ Date: 00-11-12 Qualified Person: N. Manco ✓ Date: 00-11-12	Other Instructions: Print specifications as previous Aivosin Sachet Cartons.	
ECO ANIMAL HEALTH LTD. 78 Coombe Road, New Malden, Surrey, KT3 4QS, U.K. Tel: +44 (0)20 8447 8899 Fax: +44 (0)20 8447 9292 Web: www.ecoanimalhealth.com Email: sales@ecoanimalhealth.com		

PACKAGE CONTENTS: Box contains 10 x 160-gram sachets



US06SC-1

250

Approved by FDA.

NDC 51429-160-11

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AIVLOSIN®

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

MIXING DIRECTIONS:

Aivosin® 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: 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 400-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:
NOT FOR HUMAN USE.
KEEP OUT OF REACH OF CHILDREN.

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:

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 Aivosin® 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. Wash contaminated skin.

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.

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

Read Product Information provided in the package insert carefully for complete details.

Use only as directed.

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

Aivosin® is a registered trademark of ECO Animal Health Ltd.

Pharmgate Animal Health
161 North Franklin Turnpike, Ramsey, NJ 07746

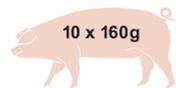
AIVLOSIN®

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

PACKAGE CONTENTS:
Box contains 10x160-gram sachets

SACHET NET WEIGHT:
Each sachet contains
160 grams Aivosin® Water Soluble Granules

Read Product Information provided in the package insert carefully for complete details



LOT: _____
EXP: _____
NON VARNISH AREA

185

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DOSAGE AND ADMINISTRATION: Swine: Control of Porcine Proliferative Enteropathy
Prepare drinking water medicated with 50 parts per million Tylvalosin as shown in the following table.

Aivosin® Water Soluble Granules sachet size	40 grams	160 grams	400 grams
Tylvalosin content of sachet (grams)	25	100	250
Recommended volume of stock solution (US gallons)	1	4	10
Volume of drinking water (US gallons)	132	528	1320
Final tyvalosin inclusion rate in drinking water	50 parts per million (ppm)		

Administer continuously in drinking water for five (5) consecutive days.

Keep water supply equipment clean and in good operating condition. Clean water medication equipment before and after each use. Do not mix or administer Tylvalosin 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.

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Distributed in the USA by: Pharmgate Animal Health,
161 North Franklin Turnpike, Ramsey, NJ 07746

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call Pharmgate Animal Health at 1-800-380-6099

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SACHET NET WEIGHT:
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160 grams Aivosin® Water Soluble Granules



ECO Animal Health
78 Coombe Road, New Malden, Surrey, KT3 4QS, U.K.
Tel: +44 (0)20 8447 8899 Fax: +44 (0)20 8447 9292
enquiries@ecoanimalhealth.com www.ecoanimalhealth.com

21

547.25

PS

THIS IS A LABEL THAT IS STUCK TO THE SIDE FACE OF THE CARTON