AIVLOSIN- tylvalosin granule
Pharmgate Animal Health

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)

NADA 141-460 Approved by FDA.

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 Type C medicated feeds must bear an expiration date of 30 days after the date of manufacture.

Crumbled Type C medicated feeds must bear an expiration date of 7 days 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).

Restricted Drug (California) - Use only as directed.

Distributed in the USA by: **Pharmgate Animal Health, LLC** 14040 Industrial Road, Omaha, Nebraska 68144

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 Pharmgate Animal Health LLC at 1-833-531-0114. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

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.

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

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

NDC 51429-170-50

Net Contents:
50 LB (22.7 Kg)

PRINCIPAL DISPLAY PANEL - 22.7 kg Bag

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Surrey, KT3 4QS, UK.

NET CONTENTS:
50 lb (22.7 kg)

Pharmgate
ANIMAL HEALTH

NDC 51429-170-50

25

25

Shaded Area = No Text Area
85mm from top of bag
Printer Tolerance +/- 25 mm

Left Gusset

Front Panel

Right Gusset

AREA FOR LOT / EXP DETAILS: 50 (wide) x 570 mm (deep). READING THIS WAY

AIVLOSIN® 17%

Approved by FDA under NADA # 141-460

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Pharmgate ANIMAL HEALTH

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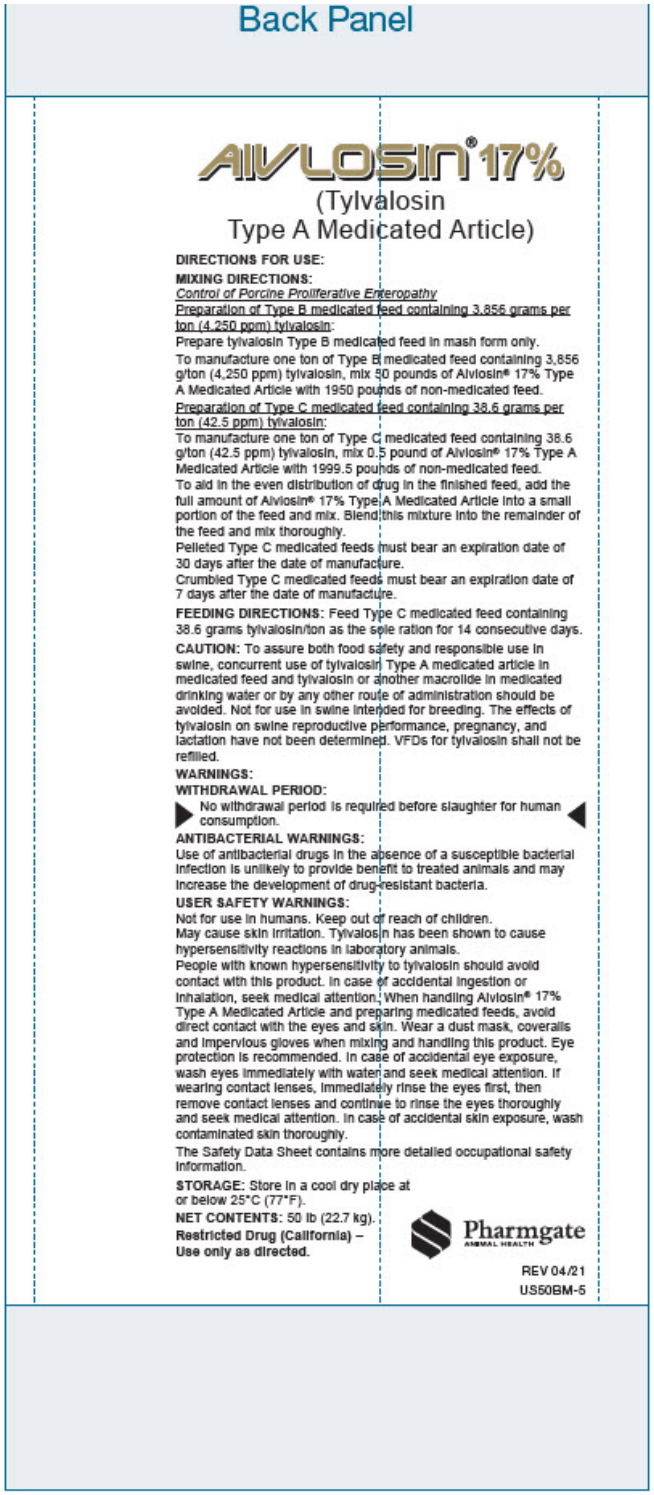
NDC 51429-170-50

AIVLOSIN® 17%

Shaded Area = No Text Area
85mm from base of bag
Printer Tolerance +/- 25 mm

▲base of bag▲

60



AIVLOSIN

tylvalosin granule

Product Information			
Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	**Item Code (Source)**	NDC:51429-170
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Tylvalosin (UNII: 9T02S42WQO) (Tylvalosin - UNII:9T02S42WQO)	Tylvalosin	170 g in 1 kg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51429-170-50	22.7 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141460	04/27/2016	

Labeler - Pharmgate Animal Health (833270817)

Registrant - ECO Animal Health (831287599)

Revised: 11/2021 Pharmgate Animal Health