Date of Approval: January 15, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG (NADA) APPLICATION

NADA 141-575

Vetmedin® Solution

(pimobendan oral solution)

Dogs

This supplement provides for the addition of the indication for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease (MMVD). Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

Sponsored by:

Boehringer Ingelheim Animal Health USA, Inc.

Executive Summary

Vetmedin® Solution (pimobendan oral solution) is approved for the delay of onset of congestive heart failure (CHF) in dogs with Stage B2 preclinical myxomatous mitral valve disease (MMVD). Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral valve regurgitation and cardiomegaly. MMVD should be diagnosed based on comprehensive physical and cardiac examinations, which should include radiography and echocardiography. The most recent (2019) consensus statement of the American College of Veterinary Internal Medicine (ACVIM) on degenerative or chronic valvular heart disease in dogs uses the term MMVD when describing acquired heart disease that is specific to the mitral valve.[1]

This supplemental approval adds a new indication to the existing fully approved Vetmedin® Solution under NADA 141-575. Vetmedin® Solution was previously approved for the management of the signs of mild, moderate, or severe CHF in dogs due to clinical MMVD or dilated cardiomyopathy (DCM), and for use with concurrent therapy for CHF (e.g., furosemide, etc.) as appropriate on a case-by-case basis.

Pimobendan is an inodilator, meaning it combines the properties of a positive inotropic agent with those of a peripheral vasodilator. By increasing myocardial contractility and dilating peripheral blood vessels, the drug reduces cardiac afterload. Pimobendan exerts its stimulatory myocardial effect by a dual mechanism of action: it increases the calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase III. The vasodilation is a result of the drug's inhibitory effect on phosphodiesterase III.

Safety and Effectiveness

The Food and Drug Administration (FDA) did not require prospective safety and effectiveness studies in dogs for this supplemental approval. The safety and effectiveness of Vetmedin® Solution in dogs is supported by the studies conducted for the original and supplemental approvals of Vetmedin® (pimobendan) chewable tablets under NADA 141-273.

Conclusions

Based on the data submitted for the supplemental approval of Vetmedin® chewable tablets, FDA determined that Vetmedin® Solution is safe and effective when used according to the labeling for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical MMVD.

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[1] Keene, B., et al. (2019) ACVIM consensus guidelines for the diagnosis and treatment of myxomatous mitral valve disease in dogs. *J Vet Intern Med*. 33(3):1127-1540.

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I. GENERAL INFORMATION

A. File Number

NADA 141-575

B. Sponsor

Boehringer Ingelheim Animal Health USA Inc.
3239 Satellite Blvd.
Duluth, GA 30096

Drug Labeler Code: 000010

C. Proprietary Name

Vetmedin® Solution

D. Drug Product Established Name

pimobendan oral solution

E. Pharmacological Category

Inodilator (calcium sensitizer and phosphodiesterase III inhibitor)

F. Dosage Form

Solution

G. Amount of Active Ingredient

1.5 mg/mL

H. How Supplied

60 mL bottle containing 50 mL solution

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Vetmedin® Solution should be administered orally at a total daily dose of 0.23 mg/lb (0.5 mg/kg) body weight. The total daily dose should be divided into 2 equal portions administered approximately 12 hours apart (i.e., morning and evening). The syringe is calibrated to deliver the appropriate morning or evening dose when drawn to the dog's nearest weight in pounds. Vetmedin® Solution should be administered directly into the mouth. Do not mix into food.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indications

Vetmedin® Solution (pimobendan oral solution) is indicated for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease. Stage B2 preclinical myxomatous mitral valve disease (MMVD) refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

Vetmedin® Solution (pimobendan oral solution) is indicated for the management of the signs of mild, moderate, or severe congestive heart failure (CHF) in dogs due to clinical MMVD or dilated cardiomyopathy (DCM). Vetmedin® Solution is indicated for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis.

N. Effect of Supplement

This supplement provides for the addition of the indication for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical MMVD. Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

II. EFFECTIVENESS

A. Dosage Characterization

This supplemental approval does not change the previously approved dosage. The FOI Summary for the original approval of NADA 141-575 dated February 13, 2024, contains dosage characterization information for dogs.

B. Substantial Evidence

The effectiveness of Vetmedin® Solution (pimobendan oral solution) for the delay of onset of CHF in dogs with Stage B2 preclinical MMVD is based on results from two multisite field studies conducted with Vetmedin® (pimobendan) chewable tablets. These studies demonstrated that Vetmedin® chewable tablets, administered at the same approved dose as Vetmedin® Solution, is effective and has an adequate safety profile in the target population. Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly. Refer to the FOI Summary for supplemental approval of Vetmedin® (pimobendan) chewable tablets (NADA 141-273) dated December 19, 2025. Vetmedin® Solution was found to be bioequivalent with Vetmedin® (pimobendan) chewable tablets in the bioequivalence study summarized in the FOI Summary for the original approval of Vetmedin® Solution (NADA 141-575) dated February 13, 2024.

III. TARGET ANIMAL SAFETY

The FDA did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-575 dated February 13, 2024, contains a summary of the study used to support target animal safety in dogs.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Vetmedin® Solution:

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans.

Wash hands after use. This product may cause eye irritation. Avoid contact with eyes. In case of contact, flush affected eye(s) immediately and thoroughly with water. If wearing contact lenses, flush the eyes first with water and then remove the lens(es) and continue to flush thoroughly with water. If eye irritation continues, seek medical advice and provide this product information to the physician.

Exposure to product may induce a local or systemic allergic reaction in sensitized individuals.

VI. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR part 514. The data demonstrate that Vetmedin® Solution, when used according to the label, is safe and effective for the effect of supplement in the General Information Section above.

A. Marketing Status

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is required to diagnose Stage B2 preclinical MMVD and to monitor for and respond to adverse reactions.

B. Exclusivity

This supplemental approval for Vetmedin® Solution qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the FD&C Act because the supplemental application included effectiveness studies. This exclusivity begins as of the date of our approval letter and only applies to the indication for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical MMVD. Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

C. Supplemental Applications

This supplement is a Category II supplement as defined in (21 CFR 514.106(b)(2)). This supplemental approval required a reevaluation of certain safety or effectiveness data in the application.

D. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.