

VETMEDIN-CA1- pimobendan tablet, chewable
Boehringer Ingelheim Animal Health USA Inc.

Vetmedin®-CA1 (pimobendan)
Chewable Tablets

Cardiac drug for oral use in dogs only

Caution:

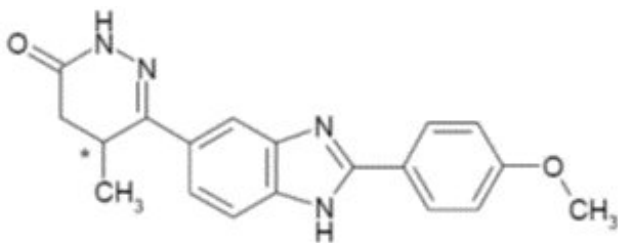
Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed.

It is a violation of Federal law to use this product other than as directed in the labeling.

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-556.

Description:

VETMEDIN-CA1 (pimobendan) is supplied as oblong half-scored chewable tablets containing 1.25 or 5 mg pimobendan per tablet. Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic drug with vasodilative properties. Pimobendan exerts a stimulatory myocardial effect by a dual mechanism of action consisting of an increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (Type III). Pimobendan exhibits vasodilating activity by inhibiting phosphodiesterase III activity. The chemical name of pimobendan is 4,5-dihydro-6-[2-(4-methoxyphenyl)-1H-benzimidazole-5-yl]-5-methyl-3(2H)-pyridazinone. The structural formula of pimobendan is:



Indications:

VETMEDIN-CA1 (pimobendan) is indicated for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease (2019 ACVIM Consensus Statement¹).

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.

Dosage and Administration:

Always provide the Client Information Sheet to the dog owner with each prescription. VETMEDIN-CA1 should be administered orally at a total daily dose of 0.23 mg/lb (0.5 mg/kg) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into 2 portions that are not necessarily equal, and the portions should be administered approximately 12 hours apart (i.e., morning and evening). The tablets are scored, and the calculated dosage should be provided to the nearest half tablet increment.

Contraindications:

Do not administer VETMEDIN-CA1 in cases of hypertrophic cardiomyopathy, aortic stenosis, or any other clinical condition where an augmentation of cardiac output is inappropriate for functional or anatomical reasons.

Do not administer VETMEDIN-CA1 to dogs with Stage A or B1 preclinical MMVD (2019 ACVIM Consensus Statement) due to the risk of cardiac pathology associated with exaggerated hemodynamic responses to VETMEDIN-CA1.

Warnings:

User Safety Warnings: 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.

Animal Safety Warnings: Keep VETMEDIN-CA1 in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

At 3 and 5 times the recommended dosage, administered over a 6-month period of time, pimobendan caused an exaggerated hemodynamic response in the normal dog heart, which was associated with cardiac pathology (**See Target Animal Safety**).

Precautions:

For use only in dogs with preclinical MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly (Stage B2 MMVD, 2019 ACVIM Consensus Statement). A diagnosis of MMVD should be made by means of a comprehensive physical and cardiac examination which should include radiography and echocardiography. Stage B2 cardiomegaly is diagnosed based on meeting all three of the following criteria:

- Radiographic vertebral heart score (VHS) >10.5, and
- Echocardiographic left atrium/aorta ratio (LA/Ao ratio) ≥ 1.6 , and
- Echocardiographic left ventricular internal diastolic diameter normalized to body weight (LVIDDN) ≥ 1.7 .

Echocardiographic examination is recommended in all cases to diagnose MMVD and confirm cardiomegaly. If therapy is initiated prior to the development of cardiomegaly, treated dogs are at risk for cardiac pathology associated with exaggerated

hemodynamic responses to VETMEDIN-CA1.

If only radiographic examination is possible, cardiomegaly may be diagnosed in cases where the VHS ≥ 11.5 and the vertebral left atrial size (VLAS) $\geq 3.01, 2$. If radiographic cardiomegaly does not meet both of these criteria, an echocardiogram should be performed prior to the initiation of therapy with VETMEDIN-CA1.

VETMEDIN-CA1 has not been evaluated in dogs receiving concomitant heart medications.

The safety of VETMEDIN-CA1 has not been established in dogs with asymptomatic heart disease caused by etiologies other than MMVD. The safe use of VETMEDIN-CA1 has not been evaluated in dogs younger than 6 months of age, dogs with congenital heart defects, dogs with diabetes mellitus or other serious metabolic diseases, dogs used for breeding, or pregnant or lactating bitches.

Adverse Reactions:

In a controlled multi-center field study, 363 dogs with preclinical MMVD (Stage B2 MMVD, 2019 ACVIM Consensus Statement) received at least one dose of VETMEDIN-CA1 (n=182) or the placebo control chewable tablets (n=181) for up to 1563 days. During this long-term study, dogs were followed until the development of congestive heart failure (CHF). Adverse reactions were seen in both treatment groups with many findings associated with the progression of MMVD and comorbidities consistent with the age of the enrolled dogs.

The median time to the primary endpoint (development of left-sided CHF or cardiac death/euthanasia) was 38% longer in the VETMEDIN-CA1 group. Despite the longer duration on study, the incidence of reported adverse reactions was similar between treatment groups.

Cough was the most frequently reported adverse reaction. This clinical finding is commonly reported in cases of MMVD and the incidence was similar between treatment groups. Lethargy, inappetence, tachypnea, collapse, arrhythmia, and syncope may also be associated with the progression of MMVD and were reported in dogs receiving VETMEDIN-CA1.

Adverse reactions not related to disease progression in dogs receiving VETMEDIN-CA1 included diarrhea, vomiting, pain, lameness, arthritis, urinary tract infection, and seizure.

Mortality rate, regardless of reason, prior to CHF was similar between the VETMEDIN-CA1 and the control groups.

Contact Information: To report suspected adverse reactions, to obtain a Safety Data Sheet (SDS), or for technical assistance, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or at <http://www.fda.gov/reportanimalae>.

Information for Dog Owners:

Always provide the Client Information Sheet with each prescription and review it with the dog owner or person responsible for care of the dog. Advise dog owners about signs of disease progression and possible adverse reactions with use of VETMEDIN-CA1.

Clinical Pharmacology:

Pimobendan is oxidatively demethylated to a pharmacologically active metabolite which is then conjugated with sulfate or glucuronic acid and excreted mainly via feces. The mean extent of protein binding of pimobendan and the active metabolite in dog plasma is >90%. Following a single oral administration of 0.25 mg/kg VETMEDIN-CA1, the maximal mean (\pm 1 SD) plasma concentrations (C_{max}) of pimobendan and the active metabolite were 3.09 (0.76) ng/mL and 3.66 (1.21) ng/mL, respectively. Individual dog C_{max} values for pimobendan and the active metabolite were observed 1 to 4 hours post-dose (mean: 2 and 3 hours, respectively). The total body clearance of pimobendan was approximately 90 mL/min/kg, and the terminal elimination half-lives of pimobendan and the active metabolite were approximately 0.5 hours and 2 hours, respectively.

Plasma levels of pimobendan and active metabolite were below quantifiable levels by 4 and 8 hours after oral administration, respectively. The steady-state volume of distribution of pimobendan is 2.6 L/kg indicating that the drug is readily distributed into tissues. Food decreased the bioavailability of an aqueous solution of pimobendan, but the effect of food on the absorption of pimobendan from VETMEDIN-CA1 is unknown.

In normal dogs instrumented with left ventricular (LV) pressure transducers, pimobendan increased LV dP/dt_{max} (a measure of contractility of the heart) in a dose dependent manner between 0.1 and 0.5 mg/kg orally. The effect was still present 8 hours after dosing. There was a delay between peak blood levels of pimobendan and active metabolite and the maximum physiologic response (peak LV dP/dt_{max}). Blood levels of pimobendan and active metabolite began to drop before maximum contractility was seen. Repeated oral administration of pimobendan did not result in evidence of tachyphylaxis (decreased positive inotropic effect) or drug accumulation (increased positive inotropic effect). Laboratory studies indicate that the positive inotropic effect of pimobendan may be attenuated by the concurrent use of a β -adrenergic blocker or a calcium channel blocker.

Reasonable Expectation of Effectiveness:

A reasonable expectation of effectiveness may be demonstrated based on evidence such as, but not limited to, pilot data in the target species or studies from published literature.

VETMEDIN-CA1 is conditionally approved pending a full demonstration of effectiveness.

Additional information for Conditional Approvals can be found at www.fda.gov/animalca.

A reasonable expectation of effectiveness for VETMEDIN-CA1 is based on results from a multi-site global field study. The study demonstrated a significant delay in the onset of congestive heart failure in dogs with cardiomegaly and heart murmur secondary to Stage B2 MMVD when treated with VETMEDIN-CA1 at the targeted total daily dose of 0.23 mg/lb (0.5 mg/kg) divided into two administrations approximately 12 hours apart.

A total of 363 dogs across various breeds were randomized to treatment. The resulting population evaluated for effectiveness consisted of 353 dogs receiving either pimobendan (VETMEDIN-CA1, n=178) or control product (placebo chewable tablets, n=175).

Dogs ranged between 6 and 17 years of age and weighed between 9 and 33 lbs at enrollment. Dogs were confirmed to have evidence of Stage B2 preclinical MMVD prior to enrollment, including a systolic heart murmur grade of $\geq 3/6$ and evidence of cardiomegaly, including a VHS >10.5 , and echocardiographic evidence of LA/Ao ratio ≥ 1.6 and LVIDDN ≥ 1.7 .

Dogs were ineligible if they were found to have current or previous evidence of cardiogenic pulmonary edema, clinically significant tachyarrhythmias, cardiac disease other than MMVD, significant systemic disease, evidence of pulmonary hypertension (RA:RV gradient > 65 mmHg), were pregnant or lactating female dogs, or if they were treated with prohibited concomitant medications for 14 or more consecutive days.

The primary outcome evaluated was a composite of the development of left-sided CHF or cardiac-related death or euthanasia. Left-sided congestive heart failure was confirmed by radiographic evidence of cardiogenic pulmonary edema. If a dog died in the absence of evidence of a non-cardiac cause of death, prior to radiographic confirmation of pulmonary edema, it was also considered to have reached the primary endpoint. The study was designed to follow individual dogs for up to 3 years or until disease progression into CHF.

At study termination, 41.6% of the dogs in the VETMEDIN-CA1 group had reached the primary endpoint, compared to 50.3% in the control group. The median time to the primary endpoint was 1228 days in the VETMEDIN-CA1 group compared to 761 days in the control group. Thus, administration of VETMEDIN-CA1 to dogs with Stage B2 preclinical MMVD resulted in the prolongation of the preclinical period by 467 days (15.6 months) compared to dogs receiving control product.

Palatability:

In a laboratory study, the palatability of VETMEDIN-CA1 was evaluated in 20 adult female Beagle dogs offered doses twice daily for 14 days. Ninety percent (18 of 20 dogs) voluntarily consumed more than 70% of the 28 tablets offered. Including two dogs that consumed only 4 and 7% of the tablets offered, the average voluntary consumption was 84.2%.

Target Animal Safety:

In a laboratory study, pimobendan chewable tablets were administered to 6 healthy Beagles per treatment group at 0 (control), 1, 3, and 5 times the recommended dosage for 6 months. See the table below for cardiac pathology results. The cardiac pathology/histopathology noted in the 3X and 5X dose groups is typical of positive inotropic and vasodilator drug toxicity in normal dog hearts and is associated with exaggerated hemodynamic responses to these drugs. None of the dogs developed signs of heart failure and there was no mortality.

Incidence of Cardiac Pathology/Histopathology in the Six-month Safety Study

Severe left ventricular hypertrophy with multifocal subendocardial ischemic lesions	One 3X and two 5X dogs ^a
Moderate to marked myxomatous thickening of the mitral valves	Three 5X dogs

Myxomatous thickening of the chordae tendineae	One 3X and two 5X dogs
Endocardial thickening of the left ventricular outflow tract	One 1X, two 3X and two 5X dogs
Left atrial endocardial thickening (jet lesions) in 2 of the dogs that developed murmurs of mitral valve insufficiency	One 3X and one 5X dog
Granulomatous inflammatory lesion in the right atrial myocardium	One 3X dog

^aMost of the gross and histopathologic findings occurred in these three dogs

Murmurs of mitral valve insufficiency were detected in one 3X (Day 65) and two 5X dogs (Days 135 and 163). These murmurs (grades II-III of VI) were not associated with clinical signs.

Indirect blood pressure was unaffected by pimobendan at the label dose (1X). Mean diastolic blood pressure was decreased in the 3X group (74 mmHg) compared to the control group (82 mmHg). Mean systolic blood pressure was decreased in the 5X group (117 mmHg) compared to the control group (124 mmHg). None of the dogs had clinical signs of hypotension.

On 24-hour Holter monitoring, mean heart rate was increased in the 5X group (101 beats/min) compared to the control group (94 beats/min). Not counting escape beats, the 3X and 5X groups had slightly higher numbers of isolated ventricular ectopic complexes (VEs). The maximum number of non-escape VEs recorded either at baseline or in a control group dog was 4 VEs/24 hours. At either Week 4 or Week 20, three 3X group dogs had maximums of 33, 13, and 10 VEs/24 hours, and two 5X group dogs had maximums of 22 and 9 VEs/24 hours. One 1X group dog with no VEs at baseline had 6 VEs/24 hours at Week 4 and again at Week 20. Second-degree atrioventricular heart block was recorded in one 3X group dog at Weeks 4 and 20, and in one dog from each of the 1X and 5X groups at Week 20. None of the dogs had clinical signs associated with these electrocardiogram changes.

Treatment was associated with small differences in mean platelet counts (decreased in the 3X and 1X groups), potassium (increased in the 5X group), glucose (decreased in the 1X and 3X groups), and maximum blood glucose in glucose curves (increased in the 5X group). All individual values for these variables were within the normal range. Three 1X and one 5X group dogs had mild elevations of alkaline phosphatase (less than two times normal).

Loose stools and vomiting were infrequent and self-limiting.

Storage Information:

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

How Supplied:

VETMEDIN®-CA1 (pimobendan) Chewable Tablets:

Available as 1.25 and 5 mg oblong half-scored chewable tablets -

50 tablets per bottle.

NDC 0010-4610-01 - 1.25 mg - 50 tablets

NDC 0010-4612-01 - 5 mg - 50 tablets

References

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.

2 Malcolm, E.L. et. al. (2018) Diagnostic value of vertebral left atrial size as determined from thoracic radiographs for assessment of left atrial size in dogs with myxomatous mitral valve disease. J AM Vet Med Assoc. 253(8):1038-1045.

Marketed by:

Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096

VETMEDIN® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH used under license.

© 2022 Boehringer Ingelheim Animal Health USA Inc. All rights reserved.

Revised 03/2022

Client Information Sheet

This Client Information Sheet contains important information about VETMEDIN-CA1 (pimobendan) Chewable Tablets. You should read this information before you start giving VETMEDIN-CA1 and review it each time the prescription is refilled as there may be new information. This sheet does not take the place of instructions from your veterinarian. Talk with your veterinarian if you do not understand any of this information or if you want to know more about VETMEDIN-CA1.

VETMEDIN-CA1 is conditionally approved by the FDA, and full demonstration of effectiveness (how well the drug works) is dependent on completion of a clinical trial. The use of conditionally approved new animal drugs is limited to a specific use, which can be found on the package insert. Additional information on conditional approval can be found at <https://www.fda.gov/animalca>.

Your veterinarian has decided to include VETMEDIN-CA1 as a part of his/her treatment plan for your dog's heart disease. Be sure to speak with your veterinarian for any questions regarding your dog's diagnosis or treatment plan.

What is VETMEDIN-CA1 and why has my veterinarian prescribed it?

VETMEDIN-CA1 contains pimobendan which helps the heart to relax and contract (pump) more effectively and it dilates blood vessels which reduces the amount of pressure the heart needs to pump blood.

Your veterinarian has prescribed VETMEDIN-CA1 because your dog has been diagnosed with myxomatous mitral valve disease (MMVD) at a stage known as B2 (see table below). Although your dog does not have any clinical signs of heart disease, VETMEDIN-CA1 can be used to delay the progression of MMVD to heart failure.

MMVD is the most common heart disease in small breed dogs but can also affect larger breeds. Early in MMVD, veterinarians may hear abnormal heart sounds (heart murmurs). MMVD is the primary cause of heart murmurs in older pets. Further testing will be needed to diagnose the stage of the disease and determine if the dog's heart is enlarged. The table below describes the stages of MMVD and the differences in possible treatments your veterinarian may prescribe.

Description of MMVD Stages and Treatments

Stage	Description	Medical Treatment
B1	<ul style="list-style-type: none"> Abnormal heart sounds (murmurs) can be heard. The dog's heart is not enlarged. There are no outward signs of heart disease. 	Medications are not currently recommended.
B2	<ul style="list-style-type: none"> Abnormal heart sounds (murmurs) can be heard. The dog's heart is enlarged (sign of disease progression). There are still no outward signs of heart disease. 	VETMEDIN-CA1 is conditionally approved for use in Stage B2.
C/D	<p>Stages C and D means the dog has been diagnosed with congestive heart failure (dog has fluid accumulation in the lungs).</p> <ul style="list-style-type: none"> Abnormal heart sounds (murmurs) can be heard. The dog's heart is enlarged. Outward signs of heart failure can be seen, such as labored breathing, increased resting respiratory rates, fainting, abnormal heart rhythms, and significant coughing. 	<p>VETMEDIN is FDA approved for use in dogs diagnosed with congestive heart failure.</p> <p>Additional medications may also be prescribed to treat the outward signs or to treat the fluid in the dog's lungs.</p>

Talk to your veterinarian if you have any questions regarding your dog's heart disease diagnosis.

Is VETMEDIN-CA1 the same as VETMEDIN?

Both products are physically identical and contain the same amount of active ingredient, pimobendan. The differences are the stage of MMVD they are used to treat and their approval status with FDA.

- VETMEDIN-CA1 is conditionally approved by the FDA to delay the onset of congestive heart failure in dogs diagnosed with Stage B2 MMVD. Further testing is being conducted to confirm effectiveness (how well the drug works).
- VETMEDIN is fully approved by the FDA to manage the outward signs of congestive heart failure. VETMEDIN is fully approved because effectiveness in dogs diagnosed with

congestive heart failure has already been confirmed and no further testing is required to evaluate how well it works for that use. Talk to your veterinarian if you have any questions about your dog's heart disease and the use of VETMEDIN-CA1.

What should I tell my veterinarian about my dog before starting VETMEDIN-CA1?

- Tell your veterinarian about other medications your pet is taking, including prescription drugs, over the counter drugs, heartworm preventives, flea & tick products, and vitamins and supplements, including herbal medications.
- Tell your veterinarian if your dog is pregnant, nursing, or you intend to breed him/her.
- Tell your veterinarian if your dog has any other serious health conditions.
- Tell your veterinarian if your dog has or develops any signs of disease progression, such as labored breathing, increased resting respiratory rates, fainting, abnormal heart rhythms, and coughing.

Talk to your veterinarian about the risks and benefits of giving VETMEDIN-CA1 to your dog.

What are some of the possible side effects of VETMEDIN-CA1?

VETMEDIN-CA1 may cause side effects, even at the prescribed dose. Contact your veterinarian immediately if your dog develops a serious or concerning medical problem or side effect while taking VETMEDIN-CA1.

The most common side effects seen in dogs with Stage B2 MMVD while taking VETMEDIN-CA1 Chewable Tablets are cough, vomiting, diarrhea, lethargy (lack of energy), and localized pain (such as in the neck or legs).

Coughing can be a sign that your dog's heart disease is progressing. Contact your veterinarian if your dog develops worsening coughing or any other sign of disease progression, including labored breathing, increased resting respiratory rates, fainting, and abnormal heart rhythms.

To report suspected adverse reactions (side effects), to obtain a Safety Data Sheet (SDS), or for technical assistance, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or at <http://www.fda.gov/reportanimalae>.

How do I give VETMEDIN-CA1 to my dog?

VETMEDIN-CA1 should be given to your dog in their mouth (orally) twice a day, about 12 hours apart. The tablets are scored so that a combination of whole or half tablets may be given to your dog. Because of differences in tablet sizes and dog sizes, the dose you are prescribed to give your dog in the morning may be the same or different from the evening dose. Please give VETMEDIN-CA1 as directed by your veterinarian.

If your dog vomits after being given VETMEDIN-CA1, please contact your veterinarian and unless directed otherwise, do not give additional tablets again until the next scheduled dose.

What if my dog receives more VETMEDIN-CA1 than what is prescribed?

Contact your veterinarian as soon as possible.

What else should I know about VETMEDIN-CA1?

VETMEDIN-CA1 is 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. It is important to show the treating physician a copy of the package insert, label, or this client information sheet. VETMEDIN-CA1 is a non-sympathomimetic, non-glycoside inotropic drug with vasodilative properties.

Keep VETMEDIN-CA1 in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

This client information sheet contains a summary of important information about VETMEDIN-CA1. For more detailed information about VETMEDIN-CA1, talk with your veterinarian.

Storage Statement: VETMEDIN-CA1 should be stored at room temperatures between 68° to 77°F (20° to 25°C). Temperature as low as 59° F (15°C) and as high as 86°F (30°C) can be acceptable for short periods of time.

Revised 03/2022

Principal Display Panel - Display Carton, 1.25 mg, 50 Tablets

NCD 0010-4610-01

Vetmedin®-CA1

(pimobendan)

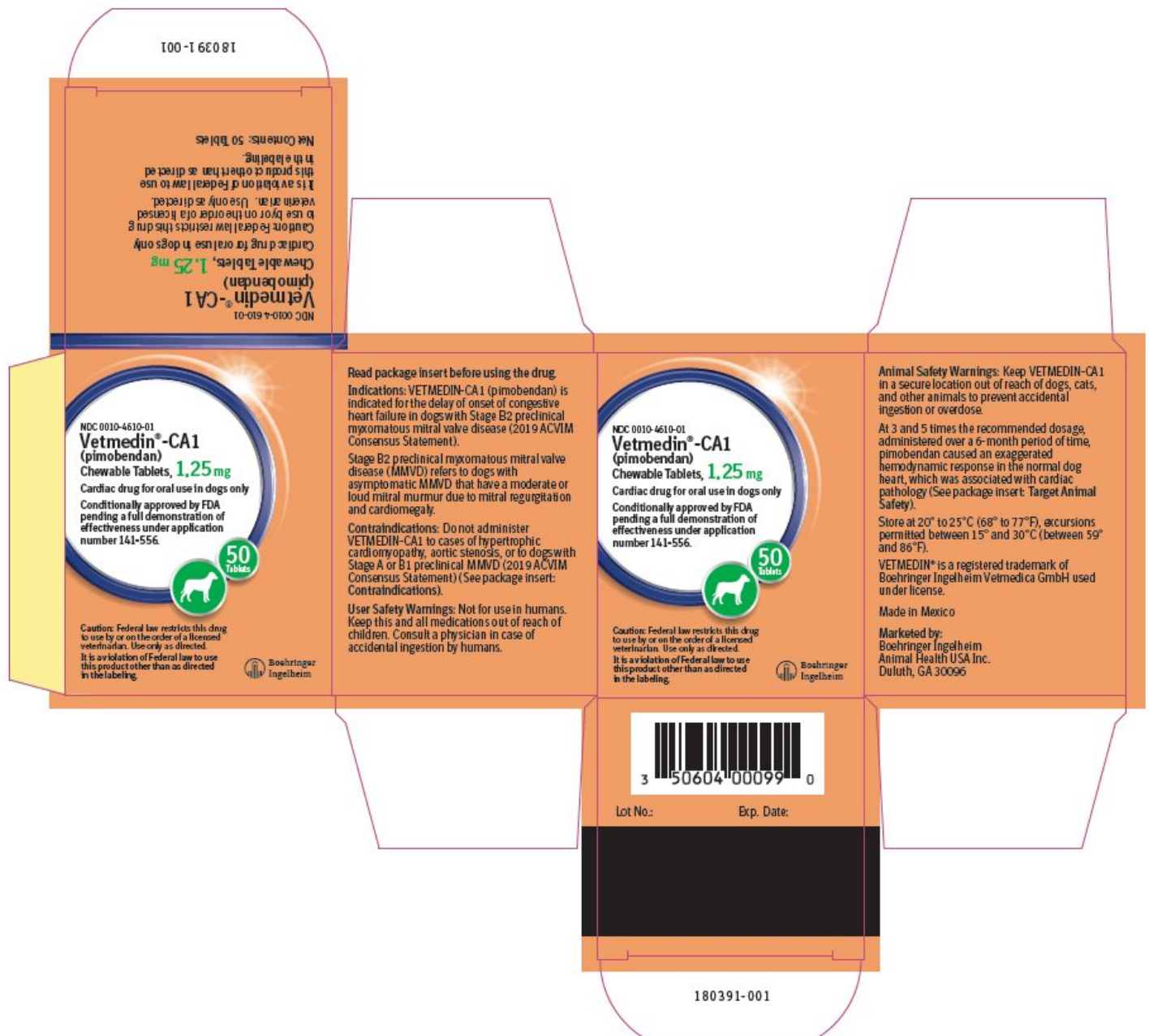
Chewable Tablets, 1.25 mg

Cardiac drug for oral use in dogs only

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-556.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal law to use this product other than as directed in the labeling.

Net Contents: 50 Tablets



Principal Display Panel - Display Carton, 5 mg, 50 Tablets

NCD 0010-4612-01

Vetmedin®-CA1

(pimobendan)

Chewable Tablets, 5 mg

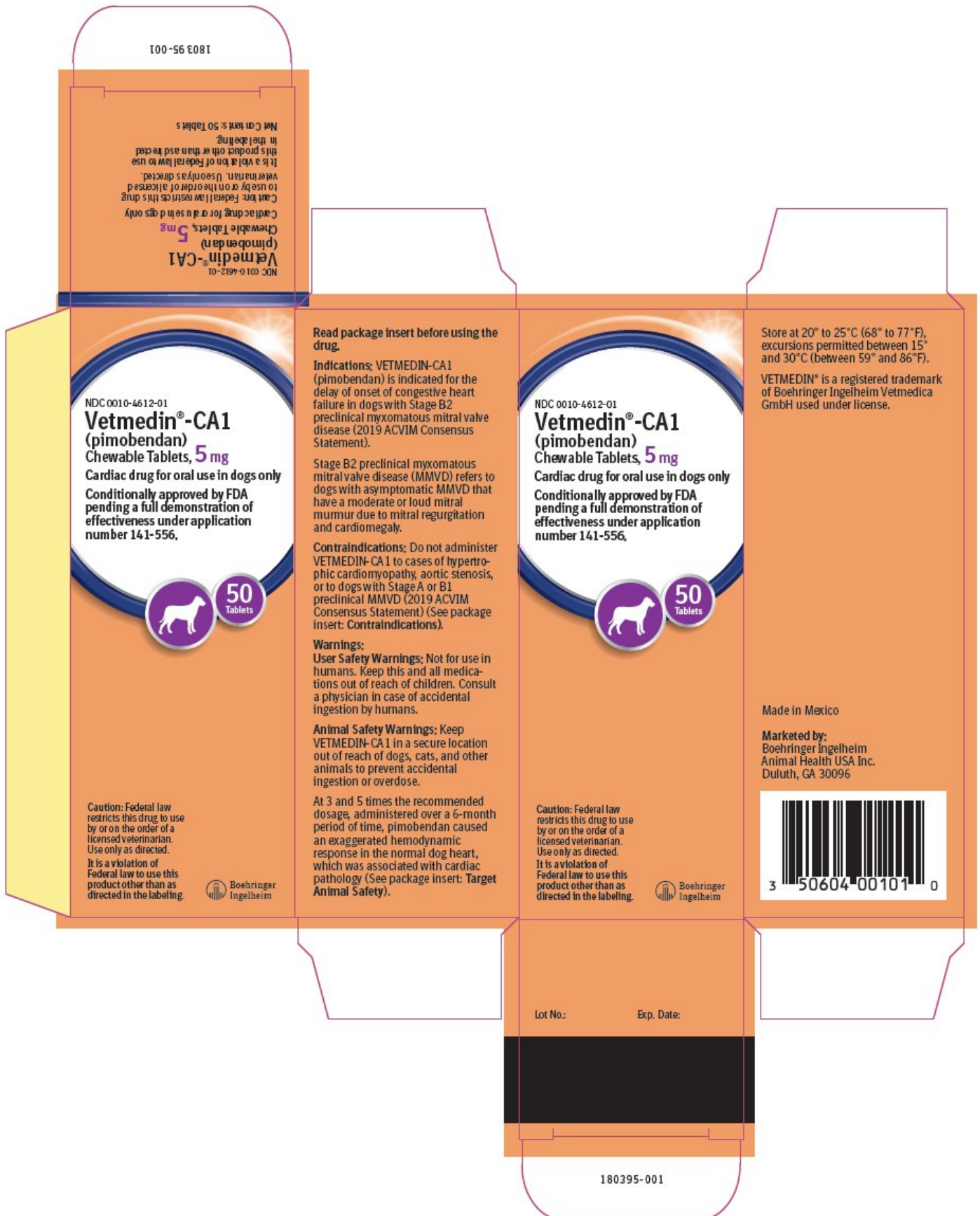
Cardiac drug for oral use in dogs only

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-556.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal law to use this product

other than as directed in the labeling.

Net Contents: 50 Tablets



VETMEDIN-CA1

pimobendan tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4610
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIMOBENDAN (UNII: 34AP3BBP9T) (PIMOBENDAN - UNII:34AP3BBP9T)	PIMOBENDAN	1.25 mg

Product Characteristics

Color	BROWN	Score	2 pieces
Shape	OVAL	Size	16mm
Flavor	MEAT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4610-01	1 in 1 CARTON		
1		50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Conditional NADA	NADA141556	07/28/2022	

VETMEDIN-CA1

pimobendan tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4612
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIMOBENDAN (UNII: 34AP3BBP9T) (PIMOBENDAN - UNII:34AP3BBP9T)	PIMOBENDAN	5 mg

Product Characteristics

Color	BROWN	Score	2 pieces
Shape	OVAL	Size	23mm
Flavor	MEAT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4612-01	1 in 1 CARTON		
1		50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Conditional NADA	NADA141556	07/28/2022	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 7/2022

Boehringer Ingelheim Animal Health USA Inc.