BECAUSE OF VETMEDIN

For 10 years, VETMEDIN has given dogs with CHF the opportunity for better days and longer lives.¹

With ongoing research and innovative support tools, we’re determined to keep making a difference.

IMPORTANT SAFETY INFORMATION: Use only in dogs with clinical evidence of heart failure. The safety of VETMEDIN has not been established in dogs with asymptomatic heart disease or in heart failure caused by etiologies other than atrioventricular valvular insufficiency or dilated cardiomyopathy. Please refer to the package insert for complete product information or visit www.vetmedin.com.

Please see Brief Summary on page [XX].

FEATURES  FUNCTIONS  BENEFITS

<table>
<thead>
<tr>
<th>VETMEDIN is available in 1.25 mg, 2.5 mg, 5 mg, and 10 mg chewable tablets</th>
<th>Allows dogs of any size to receive a suitable dose</th>
<th>Dogs’ individual needs are met</th>
</tr>
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<tr>
<td>Recommended by the American College of Veterinary Internal Medicine (ACVIM) for use in dogs with CHF at the onset of clinical signs²</td>
<td>In the QUEST* Study, dogs treated with VETMEDIN lived almost twice as long as those treated with an ACE inhibitor³</td>
<td>Owners get the most cost-effective option for their pet’s treatment</td>
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<td>* Both VetSCOPE and QUEST studies were completed using VETMEDIN Capsules. In the US, only the chewable tablets are licensed. Both the capsules and chewable tablets contain the same pharmaceutical ingredient, pimobendan, and are considered equivalent for clinical use. Bioequivalence, however, has not been shown.</td>
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I've known that Buffy has a mild heart murmur, but about a week ago she was wheezing and coughing and she deteriorated so fast. The doctor prescribed VETMEDIN, and she just turned around. It’s amazing. She’s acting more like a puppy. We could not be more delighted and grateful.

Linda Meritt—pet owner to Buffy

IMPORTANT SAFETY INFORMATION: VETMEDIN should not be given in case of hypertrophic cardiomyopathy, aortic stenosis, or any other clinical condition where an augmentation of cardiac output is inappropriate for functional or anatomical reasons. The safety of VETMEDIN has not been established in dogs with asymptomatic heart disease or in heart failure caused by etiologies other than atrioventricular valvular insufficiency or dilated cardiomyopathy. The safe use of VETMEDIN 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 in pregnant or lactating bitches. Use only in dogs with clinical evidence of heart failure. The most common side effects reported in field studies were poor appetite, lethargy, diarrhea, dyspnea, azotemia, weakness, and ataxia. If side effects should occur, pet owners should contact their veterinarian. Please refer to the package insert for complete product information or visit www.vetmedin.com.

Please see Brief Summary on page [86].
Vetmedin® (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 registered veterinarian.

Description: Vetmedin® (pimobendan) is supplied as biliol softened chewable tablets containing 1.25, 2.5, or 5 mg per tablet. Pimobendan, a benzimidazolylpentylamine, is a non-symptomatic, non-glycoside inotropic drug with vasodilatory properties. Pimobendan has a stimulatory myocardial effect due to a dual mechanism of action consisting of an increase in calcium sensitivity and a positive inotropic effect, similar to the effect of phosphodiesterase Type III. Pimobendan exhibits vasodilatory activity by inhibiting phosphodiesterase III activity. The chemical formula of pimobendan is:

\[ \text{C}_{28} \text{H}_{36} \text{N}_{12} \text{O}_{12} \text{P} \]

Indications: Vetmedin (pimobendan) is indicated for the management of the signs of mild, moderate, or severe (NYHA Class III or IV) congestive heart failure in dogs due to atroventricular valvular insufficiency (AVI) or dilated cardiomyopathy (DCM). Vetmedin is indicated for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis.

Contraindications: Pimobendan is contraindicated in dogs with congenital heart defects, dogs with diabetes mellitus or other serious metabolic diseases, dogs used for breeding, or pregnant or lactating bitches. Vetmedin should not be given in cases of hypertrophic cardiomyopathy, aortic stenosis, or other conditions where perfusion behavior of cardiac output is inappropriate for functional or anatomic reasons.

Warnings: There is a risk of drug interaction in dogs with clinical evidence of heart failure. At 3 and 5 times the recommended dosage, administered over a 6-month period of time, pimobendan and pimobendan metabolite have been associated with hepatic enzyme and serum hepatic enzyme levels. These adherent reactions were observed with concurrent administration of multifocal subendocardial granulomatous inflammatory lesion. Histopathology in the Six-month Safety Study

Table 1: CHF Death and New Arrhythmias in the 56-Day Field Study

<table>
<thead>
<tr>
<th>Group</th>
<th>DCM</th>
<th>AVVI</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>n=175</td>
<td>n=180</td>
<td>n=355</td>
</tr>
<tr>
<td>Died due to CHF</td>
<td>14.3%</td>
<td>14.4%</td>
<td>14.4%</td>
</tr>
<tr>
<td>Dogs that developed new arrhythmias*</td>
<td>39.4%</td>
<td>45.0%</td>
<td>42.3%</td>
</tr>
</tbody>
</table>

* New arrhythmias included supraventricular premature beats and tachycardia, atrial fibrillation, atroventricular conduction disturbances, ventricular premature beats and tachycardia, and bundle branch block. Following the 56-day masked field study, 137 dogs (99 dogs with AVVI or 38 dogs with DCM) were enrolled in Vetmedin in an open-label extension-use study without restrictions on concurrent therapy. The adverse reactions and clinical findings in the extended-use study were consistent with those reported in the 56-day study, with the following exception: One dog in the extended-use study developed a syncopal event following a right carotid artery surgery at Day 140 on dogs in Vetmedin and furosemide. In foreign post-approval drug experience, the following additional unusual suspected adverse reactions were reported in dogs treated with a capsule formulation of pimobendan: hemorrhage, pericardia, anemia, hyperactiveness, exercise intolerance, myoglobinuria, drooling, constipation, and diabetes mellitus.

The maximum number of non-escape VEs 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 of hypertension. On 24-hour Holter monitoring, mean heart rate was increased in the 5X group (101 beats/min) compared to the 1X group (85 beats/min). Counting escape beats, the 3X and 5X groups had slightly higher numbers of isolated ventricular ectopic complexes compared to the 1X group (14 non-escape VEs was recorded either at baseline or in a control group dog was 4 VEs/24 hours. At either Week 4 or Week 20, three 5X 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 5X dog group at Days 4 and 30, and one 3X 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: Pimobendan (pimobendan) Chewable Tablets: Store between 68°F (20°C) and 77°F (25°C), excursions permitted between 15° and 30°C (between 59° and 86°F).

How Supplied: Vetmedin® (pimobendan) Chewable Tablets of 5 mg - NDC 0010-4479-01 - 50 tablets; 10 mg - NDC 0010-4480-01 - 50 tablets; 20 mg - NDC 0010-4481-01 - 50 tablets; 30 mg - NDC 0010-4482-01 - 50 tablets. NDC 0010-4479-10 - 50 tablets

Manufactured by: Boehringer Ingelheim Pharmaco S.p.A. d.V.C. & C.V.M.

Manufactured for: Boehringer Ingelheim Vetmedica, Inc.

St. Joseph, MO 64506 U.S.A.

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44805-00 Revised 06/2013