Cardiac drug for oral use only in dogs

Caution: Federal law restrict this drug to use by or on the order of licensed veterinarians.

Description: Vetmedin® (pimobendan) is supplied as oblong, half-scored chewable tablets containing 1.25 or 5 mg pimobendan per tablet. Pimobendan, a benzimidazole-5-yl-5-methyl-3(2H)-pyridazinone, is a non-sympathomimetic, non-glycoside inotropic drug with vasodilator properties. Pimobendan exerts a stimulatory myocardial effect by a dual mechanism of action consisting of an increase in calcium sensitivity of ventricular myofibrils and inhibition of phosphodiesterase (Type III). Pimobendan exhibits vasodilatory activity by inhibiting phosphodiesterase III activity. The chemical name of pimobendan is 4,5-dihydroxy-6-(2-[4-methoxyphenyl]-1H benzimidazol-2-yl)pyridazin-3(2H)-one. The structural formula of pimobendan is:

Images of tablets are shown.

Indications: Vetmedin® is indicated for the management of the signs and symptoms of CHF, the therapy of CHF, or both. The following adverse reactions/new clinical findings are listed according to body system and are not all in order of prevalence. HF, heart failure; DO, digitalis; CHF, congestive heart failure; AVVI, atrioventricular conduction delay.

Dosage and Administration: Vetmedin should be administered 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: Vetmedin should not be given to dogs with hyperthyroidism (signs of hyperthyroidism), or any clinical condition where an alteration of cardiac output is inappropriate for functional or anatomical reasons.

Warnings: Only for use in dogs with clinical evidence of heart failure. At 3 and 5 times the recommended dosage, administration of pimobendan over a 6-month period, pimobendan caused an exaggerated hemodynamic response in the normal dog heart, which was associated with cardiac dysrhythmias (See Adverse Reactions).

Human 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.

Precautions: The safety of Vetmedin has not been established in dogs with asymptomatic heart disease or in heart failure caused by etiologies other than AIVI or DCM. 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 in dogs younger than 6 months of age, dogs with congenital heart disease or with a history of congenital heart defects, dogs with diabetes mellitus or other serious metabolic diseases, dogs used for breeding, or pregnant or lactating bitches.

Adverse Reactions: Clinical findings/adverse reactions were recorded during the 6-month safety study and are summarized as follows:

Cardiac drug chewable tablets were administered to 6 healthy Beagles per treatment group at the start of the study, 1, 3, and 5 times the recommended dosage for 6 months. See Table 3 for cardiac pathology results. The cardiac pathology/ histopathology findings 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 were no other pharmacological findings.

Vetmedin® (pimobendan) Chewable Tablets

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

Table 2: Effectiveness Results for the 56-Day Field Study

Table 3: Incidence of Cardiac Pathology/ Histopathology in the Six month Safety Study

Note: Most of the gross and histopathological findings occurred in these dogs.

Murmurs of mitral valve insufficiency were detected in one 3X dog and two 5X dogs (Dogs 123 and 136). These murmurs ranged from II-V of II at baseline to IV-V at 6 months for several of the 5X dogs.

Table 2: Adverse Events in the 56-Day Field Study

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