

## Vetmedin 5 mg hard capsules

**Species:**Dogs

**Therapeutic indication:Pharmaceuticals:** Cardiovascular and respiratory preparations

**Active ingredient:**Pimobendan

**Product:**Vetmedin® 5 mg hard capsules

**Product index:**Vetmedin hard capsules

## Presentation

Hard capsules white to orange in colour, containing 5 mg pimobendan per capsule as active substance and titanium Dioxide (E171) 1.2320 mg/capsule and Sunset Yellow (E110) 0.3080 mg/capsule as excipients.

## Uses

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

When used in cases of valvular insufficiency in conjunction with frusemide, the product has been shown to improve the quality of life and extend life expectancy in treated dogs.

When used in a limited number of cases of dilated cardiomyopathy in conjunction with frusemide, enalapril and digoxin, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

## Dosage and administration

See dosing table below.

### Vetmedin 5 mg Capsules Dosage Guide

Bodyweight (kg)	Daily Dosage (mg)	No. of 5 mg capsules per administration	
		Morning	Evening
21-40	10	1	1
41-60	20	2	2
>60	30	3	3

Vetmedin capsules should be administered orally (approximately one hour before feeding) at a dose of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The daily dose should be divided into two equal administrations, one half of the dose given in the morning and the other half approximately 12 hours later.

Determine the bodyweight accurately before prescribing to ensure administration of the correct dosage.

In cases of mild congestive heart failure, a daily dosage at the lower end of the dose range may be adequate. If, however, a clear response is not observable within one week, the dosage should be raised.

Vetmedin capsules may be combined with a diuretic treatment such as frusemide.

### **Contra-indications, warnings, etc**

Vetmedin capsules should not be used in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).

### **Special precautions for use in animals**

The product should only be used in dogs with cardiac insufficiency. Do not exceed the recommend dosage.

### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and may be avoided by reducing the dose in these cases. In rare cases transient diarrhoea, anorexia or lethargy have been observed.

In studies with rats and rabbits, pimobendan had no effect on fertility and embryotoxic effects occurred only at maternotoxic doses. In experiments with rats it has been shown that pimobendan is excreted into milk.

No information is available on the safety of Vetmedin in pregnant and lactating bitches. Therefore, Vetmedin capsules should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.

The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the  $\beta$ -antagonist propranolol. In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected.

In the case of overdose, symptomatic treatment should be initiated.

### **Pharmaceutical precautions**

Shelf life of the veterinary medicinal product as packaged for sale : 3 years.

Do not store above 25°C. Store in a dry place. Store in tightly closed original container.

Keep out of the reach and sight of children. For animal treatment only.

To be supplied only on veterinary prescription.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

### Legal category

Legal category: POM-V

### Packaging quantities

Vetmedin 5.0 mg capsules are presented in white high density polyethylene bottles with white polypropylene child-resistant screw-caps OR white polypropylene bottle with white polypropylene child resistant screw-caps. Each bottle contains 100 capsules and is packed in a cardboard carton. Not all presentations may be marketed.

### Further information

### Pharmacodynamic properties

Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilative properties. Pimobendan exerts its stimulatory myocardial effect by a mechanism of action: increases in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (type III). It also exhibits a vasodilatory action through an inhibitory action on phosphodiesterase III activity. The combined evidence from cell culture, laboratory animal and small studies in the target species suggests that the combination of the specific PD properties of pimobendan may reduce the progression of myocardial damage in dogs with MVD and DCM when used together with other standard therapy.

### Pharmacokinetic particulars

Absorption Following oral administration of Vetmedin capsules the absolute bioavailability of the active principle is 60 – 63%. Since this bioavailability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 1 hour before feeding.

Distribution The volume of distribution is 2.6 l/kg, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding is 93%

Metabolism The compound is oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II conjugates of UD-CG-212, in essence glucuronides and sulphates.

Elimination The plasma elimination half-life of pimobendan is  $0.4 \pm 0.1$  hours which is consistent with a high clearance of  $90 \pm 19$  ml/min/kg and a short mean residence time of  $0.5 \pm 0.1$  hours.

The main active metabolite is eliminated with a plasma elimination half-life of  $2.0 \pm 0.3$  hours. Almost the entire dose is eliminated via faeces.

### Marketing Authorisation Number

Vm 08327/4316

## Significant changes

### GTIN

**GTIN description:** Vetmedin 5 mg hard capsules

**GTIN:** 5012917025118

**Boehringer Ingelheim Animal Health UK Ltd**

**Telephone:** Technical Enquiries: 01344 746957

**Email:** [vetenquiries@boehringer-ingelheim.com](mailto:vetenquiries@boehringer-ingelheim.com)