

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

### Active Substance

Pimobendan	5.00	mg
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### Excipients

Titanium Dioxide (E171)	1.232	mg
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Sunset Yellow (E110)	0.308	mg
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For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Hard capsule, orange/white in colour.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dog.

### 4.2 Indications for use, specifying the target species

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 large breed dogs in conjunction with concomitant standard therapy, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

### **4.3 Contraindications**

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).

### **4.4 Special warnings for each target species**

None known.

### **4.5 Special precautions for use**

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

This product should only be used in dogs with cardiac insufficiency. Do not exceed the recommended dose.

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

None known

### **4.6 Adverse reactions (frequency and seriousness)**

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.

### **4.7 Use during pregnancy, lactation or lay**

In studies with rats and rabbits pimobendan had no effect on fertility and embryotoxic effects only occurred 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.

### **4.8 Interaction with other medicinal products and other forms of interaction**

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.

#### 4.9 Amounts to be administered and administration route

See dosing guide below.

Vetmedin capsules should be administered orally (approximately one hour before feeding) at a dose of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The daily dose should be divided into two equal administrations; one half of the dose 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 dose 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.

#### Dosing guide:

Note: for smaller dogs, Vetmedin 1.25 mg or 2.5 mg capsules are more suitable.

<b>Daily Pimobendan Dosage: 0.2 – 0.6 mg/kg</b>							
		<b>No. of capsules per administration</b>					
		<b>Morning</b>			<b>Evening</b>		
<b>Body Weight (kg)</b>	<b>Daily Dosage (mg)</b>	<b>1.25 mg</b>	<b>2.5 mg</b>	<b>5 mg</b>	<b>1.25 mg</b>	<b>2.5 mg</b>	<b>5 mg</b>
< 10	2.5	1	-	-	1	-	-
10-20	5	-	1	-	-	1	-
21-40	10	-	-	1	-	-	1
41-60	20	-	-	2	-	-	2
> 60	30	-	-	3	-	-	3

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

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

In case of overdose symptomatic treatment should be initiated.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Cardiac stimulant, phosphodiesterase inhibitor.

ATCvet code: QC01CE90

#### **5.1 Pharmacodynamic properties**

Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.

Pimobendan exerts its stimulatory myocardial effect by a dual mode of action: it increases calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through inhibition of phosphodiesterase III activity.

#### **5.2 Pharmacokinetic particulars**

##### Absorption:

Following oral administration of Vetmedin capsules the absolute bio-availability of the active principle is 60 - 63%. Since this bio-availability 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.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Citric acid anhydrous  
Colloidal Silica  
Microcrystalline Cellulose  
Povidone  
Magnesium Stearate  
Titanium Dioxide (E171)  
Sunset Yellow (E110)  
Gelatin

### **6.2 Major incompatibilities**

None known.

### **6.3 Shelf-life**

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

### **6.4 Special precautions for storage**

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

### **6.5 Nature and composition of immediate packaging**

Vetmedin 5.0 mg capsules are presented in either white polypropylene bottles with white polypropylene child-resistant screw-caps with high density polyethylene inner caps and polypropylene spacer or in white high density polyethylene bottles with white polypropylene child-resistant screw-caps. Each bottle contains 100 capsules and is packed in a cardboard carton.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Unused product or waste materials should be disposed of in accordance with the current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH  
Binger Strasse 173  
55216 Ingelheim am Rhein  
Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10454/021/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> October 1999

Date of last renewal: 20<sup>th</sup> July 2009

## **10 DATE OF REVISION OF THE TEXT**

May 2018