SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Active substance:
Pimobendan 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Titanium Dioxide (E171)	1.2320 mg
Sunset Yellow (E110)	0.3080 mg
Citric Acid Anhydrous	
Colloidal Silica	
Microcrystalline Cellulose	
Povidone	
Magnesium Stearate	
Gelatin	

Capsule, hard.
Orange/ white colour

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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 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.

3.3 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).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
This veterinary medical 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
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dog:

Rare (1 to 10 animals / 10,000 animals treated):	A moderate positive chronotropic effect and vomiting.[1] Transient diarrhoea, anorexia or lethargy

[1] These effects are dose-dependent and can be avoided by reducing the dose in these cases.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

In studies with rats and rabbits pimobendane 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 this veterinary medical product in pregnant and lactating bitches. Therefore, this veterinary medical product should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.

3.8 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 β-antagonist propranolol.
In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected.

3.9 Administration routes and dosage

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 perday. The daily dose should be divided into two equal administrations: onehalf 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.

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

This veterinary medical product may be combined with a diuretic treatment such as frusemide.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QC01CE90

4.2 Pharmacodynamics

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 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.

4.3 Pharmacokinetics

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 ± 0.1 hours which is consistent with a high clearance of 90 ± 19 m1/min/kg and a short mean residence time of 0.5 ± 0.1 hours.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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. The capsules may also be presented in aluminium/polyethylene strips which are then packed into a cardboard carton containing 100 capsules.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5010
Vm 61700/3010

8. DATE OF FIRST AUTHORISATION

21 July 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 02 December 2025