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

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 (E71)	1.232 mg
Sunset Yellow (E110)	0.308 mg
Citric acid anhydrous Colloidal	
Silica Microcrystalline Cellulose	
Povidone	
Magnesium Stearate Titanium	
Gelatin	

Hard capsule, orange/white in 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 veterinary medicinal 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 veterinary medicinal product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

3.3 Contraindications

The veterinary medicinal product 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:

The veterinary medicinal 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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Increased heart rate[1,2] Vomiting[1], diarrhoea[3], anorexia, lethargy

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

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

Pregnancy, lactation and fertility:
Laboratory studies in 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 this veterinary medical productin 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

Oral use.

See dosing guide below.

The veterinary medicinal product 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

The veterinary medicinal 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 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.

4.3 Pharmacokinetics

Absorption:
Following oral administration of the veterinary medicinal product 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.
Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is 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.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 NUMBER(S)

VPA10454/021/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

06/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).