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

Titanium Dioxide (E171) 1.2320 mg/capsule
Sunset Yellow (E110) 0.3080 mg/capsule

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule, hard
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 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.

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

i Special precautions for use in animals

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

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

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

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 β-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 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 thedose range may be adequate. If, however, a clear response is not observable within one week, the dosage should be raised.

4.9 Amounts to be administered and administration route (Cont/d)

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

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 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 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 gogs with MVD and DCM when used together with other standard therapy.

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 ± 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Colloidal Silica
Microcrystalline cellulose.
Povidone
Magnesium Stearate

Capsule shell
Titanium Dioxide (E171)
Sunset Yellow (E110)
Gelatin

6.2 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^{o}C.
Store in a dry place.
Store in tightly closed original container.

6.5 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 presentations may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4316

9. DATE OF FIRST AUTHORISATION

21 July 1999

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 09 November 2018