

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x carton containing 100 x 5 mg capsules

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg hard capsules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each capsule contains 5 mg pimobendan with titanium dioxide 1.2320 mg/capsule and sunset yellow FCF 0.3080 mg/capsule as colouring agents.

3. PHARMACEUTICAL FORM

Hard capsules.

4. PACKAGE SIZE

100 capsules.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Treatment of congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency in dogs. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 halves, one half of the dose in the morning and the other half approximately 12 hours later. 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.

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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Only for use in dogs with cardiac insufficiency. 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). 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. The pimobendan-induced contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the β -antagonist propranolol.

For further information on dosage, administration, user precautions, contraindications and warnings – see package leaflet.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in tightly closed original container.

Store in a dry place. To be supplied only on veterinary prescription.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBERS

Vm 08327/4316

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1 x bottle containing 100 x 5 mg capsules

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg hard capsules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each capsule contains 5 mg pimobendan with titanium dioxide 1.2320 mg/capsule and sunset yellow FCF 0.3080 mg/capsule as colouring agents.

3. PHARMACEUTICAL FORM

Hard capsules.

4. PACKAGE SIZE

100 capsules.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Treatment of congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency in dogs. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 halves, one half of the dose in the morning and the other half approximately 12 hours later.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Only for use in dogs with cardiac insufficiency. 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). 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. The pimobendan-induced contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the β -antagonist propranolol.

For further information on dosage, administration, user precautions, contraindications and warnings – see package leaflet.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in the carton.
Store in tightly closed original container. Store in a dry place. To be supplied only on veterinary prescription.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBERS

Vm 08327/4316

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: Vetmedin 5 mg hard capsules

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

The Marketing Authorisation for Vetmedin is held by:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer:
Klocke Pharma Service GmbH
D 77767 Appenweier, Germany.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg hard capsules

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each capsule contains pimobendan as the active ingredient and also contain the colouring agents titanium dioxide 1.2320 mg/capsule and sunset yellow FCF 0.3080 mg/capsule.

4. INDICATION(S)

Vetmedin belongs to a group of medicines which help the weakened heart to pump blood around the body.

How Vetmedin Helps Your Dog

In a range of heart conditions, for example where the heart valves are leaky or where the heart is enlarged, blood is less efficiently pumped around the body. Vetmedin helps the circulation of blood by strengthening the heart muscle. It should only be administered to dogs with heart problems.

5. CONTRAINDICATIONS

Before Giving Vetmedin

Tell your Veterinary Surgeon if:

- Your dog is pregnant or has recently had puppies
- Your dog is taking any other drug
- Your dog has reacted badly to previous related medication

If in doubt, ask your Veterinary Surgeon.

Information for the Veterinary Surgeon:

Contra-indications and warning

Only for use in dogs with cardiac insufficiency. 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.

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 (eg aortic stenosis). 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 mechanism of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (type III). It also exhibits a vasodilating 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. 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. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the b-antagonist propranolol. 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 in pregnant and lactating bitches. In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. 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 increased.. Following oral administration of Vetmedin capsules, the absolute bioavailability of the active principle is 60–63%. Bioavailability is considerably reduced when pimobendan is administered with food or shortly thereafter. Hence it is recommended to be given 1 hour before feeding. The mean plasma binding is 93%. The plasma elimination half-life is approximately 30 minutes and the mean metabolite elimination half-life is approximately 2 hours.

Almost the entire dose is eliminated via the faeces. To be supplied only on veterinary prescription.

6. ADVERSE REACTIONS

After Giving Vetmedin

All medicines sometimes cause side effects. In rare cases Vetmedin may cause vomiting. If this is severe or if you observe any other symptoms, stop treatment and consult your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

How to Give Vetmedin

The usual recommended dosage is shown in the table below. The total daily dose should be divided into two equal administrations; one half should be given in the morning and the other half approximately 12 hours later. Vetmedin should be given by mouth (approximately 1 hour before feeding). Your vet may give alternative advice in special circumstances as the minimum effective dose may vary in individual animals.

Daily Pimobendan Dosage: 0.2 – 0.6 mg/kg			
		No. of capsules per administration	
Body Weight (kg)	Daily Dosage (mg)	Morning 5.0 mg	Evening 5.0 mg
< 10	2.5	-	-
10-20	5	-	-
21-40	10	1	1
41-60	20	2	2
> 60	30	3	3

9. ADVICE ON CORRECT ADMINISTRATION

Vetmedin Capsules may be combined with a diuretic treatment such as frusemide. Do not administer other medication without first consulting your veterinary surgeon. Do not give more than the recommended dosage. Determine the bodyweight accurately before treatment to ensure correct dosage. In the event of overdosage consult a veterinary surgeon immediately.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.

Do not store above 25°C.

Store in tightly closed original container.

Store in a dry place.

Do not give this medicine after the expiry date which you will find printed on the packaging.

12. SPECIAL WARNING(S)

In the event of accidental ingestion, seek medical advice and show this leaflet or the label to the doctor.

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

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

This leaflet was revised in December 2011.

15. OTHER INFORMATION

Please read this leaflet carefully before giving this medicine to your dog. If you have any questions, speak to your Veterinary Surgeon.

The name of this medicine is Vetmedin capsules.

Each box of Vetmedin contains 100 capsules packed in a bottle with child resistant screw cap.

Vetmedin can only be obtained with a prescription from your veterinary surgeon. Any enquiries relating to this product should be directed through the prescribing veterinary surgeon.

Vm 08327/4316

POM-V

To be supplied only on veterinary prescription.

Approved: 09 November 2018

