SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active substance:	
Pimobendan	1.25 mg
Excipients:	
Colorants:	
Titanium dioxide (E171)	0.9760 mg
Yellow iron oxide (E172)	0.0439 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard.

Oblong hard gelatine capsule with a light yellow cap and a white opaque body.

4. CLINICAL PARTICULARS

4.1. Target species

Dogs

4.2. Indications for use, specifying the target species

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid regurgitation).

4.3. Contraindications

Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an increase of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).
Do not in dogs with severe hepatic insufficiency since pimobendan is metabolised mainly in the liver.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings for each target species

Absorption of this product is modified when administered with food. Therefore, the optimum efficacy is obtained when the stomach is empty. The product should be given one hour before feeding.

4.5. Special precautions for use

Special precautions for use in animals
In diabetic animals, glucose levels have to be strictly controlled.

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.

4.6. Adverse reactions (frequency and seriousness)

In rare cases (more than 1 but less than 10 animals in 10,000 animals), gastrointestinal adverse reactions, such as vomiting and diarrhoea, systemic reactions such as lethargy and anorexia and cardiovascular system disorders such as moderate positive chronotropic effects have been reported.
Signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment, in very rare cases. These signs disappear when the treatment is withdrawn.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7. Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any effect on fertility, and embryotoxic effects only occurred at maternotoxic doses. Laboratory studies in rats have shown that pimobendan is excreted into milk. Therefore, the use is only recommended during pregnancy and lactation if the expected therapeutic benefits outweigh the potential risk.

4.8. Interaction with other medicinal products and other forms of interaction

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the ß-antagonist propranolol.

4.9. Amounts to be administered and administration route

Oral use.
The veterinary medicinal product should be administered at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The preferable daily dose is 0.5 mg pimobendan/kg body weight. The daily dose should be divided into two administrations (0.25 mg/kg each), one half of the dose in the morning and the other half approximately 12 hours later. Each dose should be given approximately one hour before feeding.

Body weight (kg)	Pimobendan daily dose (mg)	Vetmedin 1.25 mg No. capsules/adm		Vetmedin 2.5 mg No. capsules/adm		Vetmedin 5 mg No. capsules/adm	
		Morning	Afternoon	Morning	Afternoon	Morning	Afternoon
< 8	2,5	1	1	-	-	-	-
8 – 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 furosemide or torasemide.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

The administration of twice the therapeutic dose (1 mg pimobendan/kg body weight) may produce moderate positive chronotropic effects and vomiting. In such situations, treatment should be interrupted until symptoms disappear and then the product should be used at the recommended dose.

4.11. Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cardiac stimulants excluded cardiac glycosides. Phosphodiesterase inhibitors.
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 is a racemic mixture of two stereoisomers. The (-)-enantiomer is the active compound of the mixture.
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). However, the mechanism of action of calcium sensitivity is not totally clear.
It also exhibits a vasodilating action through an inhibitory action on phosphodiesterase III activity and exerts an antithrombotic effect through the inhibition of the plaquetary aggregation.

Pimobendan improves the cardiac relaxation exerting a lusotropic positive effect.

5.2. Pharmacokinetic particulars

Absorption:
Following oral administration of Vetmedin capsules the absolute biovailability of the active ingredient is 60 - 63 %. Since this bioavailability 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 in the steady state is 2.6 l/kg after intravenous administration, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding in vitro is 93 %.

Metabolism:
The compound is oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II, glucuronides and sulfates.

Elimination:
The plasma elimination half-life of pimobendan is 0.4 ± 0.1 hours, consistent with the high clearance of 90 ± 19 ml/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.

After oral administration, the plasma elimination half-life of pimobendan and its major active metabolite is 0.7 ± 0.1 and 1.9 ± 0.4 hours, respectively.

The compound is excreted principally with faeces and in less proportion with urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Silica, colloidal anhydrous
Cellulose microcrystalline
Povidone
Magnesium stearate
Gelatine
Titanium dioxide (E171)
Yellow iron oxide (E172)

6.2. Major incompatibilities

Not applicable.

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 25ºC.
Keep the bottle tightly closed.

6.5. Nature and composition of immediate packaging

White high-density polyethylene bottles. Each bottle is closed with a child-resistant closure of polypropylene.

Package size:

One bottle containing 100 capsules in a folding carton.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/11/2003
Date of last renewal: [To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally.]

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg capsules
pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Each capsule contains:

Pimobendan 1.25 mg
Titanium dioxide (E171)
Yellow iron oxide (E172)

3. PHARMACEUTICAL FORM

Capsule, hard.

4. PACKAGE SIZE

100 capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 ºC.
Keep the bottle tightly closed.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg capsules
pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Pimobendan 1.25 mg

3. PHARMACEUTICAL FORM

Capsule, hard.

4. PACKAGE SIZE

100 capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 ºC.
Keep the bottle tightly closed.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET:
Vetmedin 1.25 mg capsules

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

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim/Rhein
Germany

Manufacturer for the batch release:
Klocke Pharma Service GmbH
Strassburger Strasse 77
D-77767 Appenweier
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg capsules
Pimobendan

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

Pimobendan 1.25 mg
Titanium dioxide (E171)
Yellow iron oxide (E172)

Oblong hard gelatine capsule with a light yellow cap and a white opaque body.

4. INDICATION(S)

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid regurgitation).

5. CONTRAINDICATIONS

Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an increase of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).
Do not use in dogs with severe hepatic insufficiency since pimobendan is metabolised in the liver.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In rare cases (more than 1 but less than 10 animals in 10,000 animals), gastrointestinal adverse reactions, such as vomiting and diarrhoea, systemic reactions such as lethargy and anorexia and cardiovascular system disorders such as moderate positive chronotropic effects have been reported.

Signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment, in very rare cases. These signs disappear when the treatment is withdrawn.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

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

Oral use.
The veterinary medicinal productshould be administered at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The preferable daily dose is 0.5 mg pimobendan/kg body weight. The daily dose should be divided into two administrations (0.25 mg/kg each), one half of the dose in the morning and the other half approximately 12 hours later. Each dose should be given approximately one hour before feeding.

Body weight (kg)	Pimoben-dan Daily dose (mg)	Vetmedin 1.25 mg No.capsules/ administration		Vetmedin 2.5 mg No.capsules/ administration		Vetmedin 5 mg No.capsules/ administration	
		Morning	Afternoon	Morning	Afternoon	Morning	Afternoon
<8	2,5	1	1			-	-
8-20	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 furosemide or torasemide.

9. ADVICE ON CORRECT ADMINISTRATION

Each dose should be administered approximately one hour before feeding.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25ºC.
Keep the bottle tightly closed.

12. SPECIAL WARNINGS

Special warnings for each target species:
Absorption of this product is modified when administered with food. Therefore, the optimum efficacy is obtained when the stomach is empty. The product should be given one hour before feeding.

Special precautions for use in animals:
In diabetic animals, glucose levels have to be controlled strictly.

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.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any effect on fertility, and embryotoxic effects only occurred at maternotoxic doses. Laboratory studies in rats have shown that pimobendan is excreted into milk. Therefore, the use is only recommended during pregnancy and lactation if the expected therapeutic benefits outweigh the potential risk.

Interaction with other medicinal products and other forms of interaction:
In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the ß-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):
The administration of twice the therapeutic dose (1 mg pimobendan/kg body weight) may produce moderate positive chronotropic effects and vomiting. In such situations, treatment should be interrupted until symptoms disappear and then the product should be used at the recommended dose.

Incompatibilities:
Not applicable.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. The measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[To be completed nationally.]

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

Package size:
One bottle containing 100 capsules in a folding carton.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.