

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin Chew 2.5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)  
Vetmedin vet. 2.5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)  
Vetmedin S 2.5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

### Active substance:

Pimobendan 2.5 mg

### Excipients:

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Chewable tablet.

Brownish, oval, divisible tablet, scored on both sides.

The tablet can be divided into two equal parts.

## 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 valve regurgitation).  
(See also section 4.9).

For the treatment of dilated cardiomyopathy in the preclinical stage (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter) in Doberman Pinschers following echocardiographic diagnosis of cardiac disease (see sections 4.4 and 4.5).

For the treatment of dogs with myxomatous mitral valve disease (MMVD) in the preclinical stage (asymptomatic with a systolic mitral murmur and evidence of increased heart size) to delay the onset of clinical symptoms of heart failure (see sections 4.4 and 4.5).

### 4.3 Contraindications

Do not use pimobendan in hypertrophic cardiomyopathies or in diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).

Since pimobendan is metabolised mainly via the liver, it should not be used in dogs with severe impairment of liver function.

(See also section 4.7).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings for each target species

The product has not been tested in cases of asymptomatic DCM in Dobermans with atrial fibrillation or sustained ventricular tachycardia.

The product has not been tested in cases of asymptomatic myxomatous mitral valve disease in dogs with significant supraventricular and/or ventricular tachyarrhythmia.

## 4.5 Special precautions for use

### Special precautions for use in animals

The blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus. For use in the preclinical stage of dilated cardiomyopathy (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter), a diagnosis should be made by means of a comprehensive cardiac examination (incl. echocardiographic examination and possibly Holter monitoring).

For use in the preclinical stage of myxomatous mitral valve disease (stage B2, according to ACVIM consensus: asymptomatic with mitral murmur  $\geq 3/6$  and cardiomegaly due to myxomatous mitral valve disease), a diagnosis should be made by means of a comprehensive physical and cardiac examination which should include echocardiography or radiography where appropriate. (See also section 5.1).

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan. (See also section 4.6).

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

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

Wash hands after use.

To avoid accidental ingestion of the product by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the cardboard box.

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

Advice to doctors: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

## 4.6 Adverse reactions (frequency and seriousness)

In rare cases a slight positively chronotropic effect (rise in heart rate) and vomiting can occur. However, these effects are dose-dependent and can be avoided by reducing the dose.

In rare cases transient diarrhoea, anorexia or lethargy have been observed.

In rare cases, an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.

Although a relationship with pimobendan has not been clearly established, in very rare cases, signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment. 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).

## 4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects. However, these studies have shown evidence of maternotoxic and embryotoxic effects at high doses, and have also shown that pimobendan is excreted into milk. The safety of the product has not been assessed in pregnant or nursing bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.

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

In pharmacological studies no interaction between the cardiac glycoside ouabain (strophanthin) and pimobendan was observed. The pimobendan-induced increase in cardiac contractility is attenuated by the calcium antagonists verapamil and diltiazem and by the  $\beta$ -antagonist propranolol.

#### **4.9 Amounts to be administered and administration route**

Oral use.

Determine the bodyweight accurately before treatment to ensure correct dosage.

A dosage range of 0.2 mg to 0.6 mg pimobendan/kg body weight, divided into two daily doses, should be respected.

The preferable daily dose is 0.5 mg pimobendan/kg body weight, divided into two daily doses.

For a body weight of 10 kg, this corresponds to one 2.5 mg chewable tablet in the morning and one 2.5 mg chewable tablet in the evening.

Do not exceed the recommended dosage.

Administration of pimobendan should take place approximately one hour before feeding.

Pimobendan may also be used in combination with a diuretic, e.g. furosemide or torasemide.

To allow accurate dosing according to body weight, the chewable tablet can be halved along the designated score line.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

An overdose may cause a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

In prolonged exposure (6 months) of healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed in some dogs. These changes are of pharmacodynamic origin.

#### **4.11 Withdrawal period**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Cardiac stimulants excl. cardiac glycosides, phosphodiesterase inhibitors

ATCvet Code: QC01CE90

#### **5.1 Pharmacodynamic properties**

Pimobendan, a benzimidazole-pyridazinone derivative has a positively inotropic action and possesses pronounced vasodilator properties.

The positive inotropic effect of pimobendan is mediated by a dual mechanism of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase III. Thus the positive inotropism is triggered neither by an action similar to that of the cardiac glycosides nor sympathomimetically.

The vasodilator effect arises from inhibition of phosphodiesterase III.

When used in cases of symptomatic valvular insufficiency in conjunction with furosemide 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 symptomatic dilated cardiomyopathy in conjunction with furosemide, enalapril and digoxin, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

In a randomized and placebo controlled study in 363 dogs with preclinical myxomatous mitral valve disease, all dogs met the following inclusion criteria: age  $\geq$  6 years, bodyweight  $\geq$  4.1 and  $\leq$  15 kg, characteristic systolic heart murmur of moderate to high intensity ( $\geq$  grade 3/6) with maximal intensity over the mitral area; echocardiographic evidence of advanced myxomatous mitral valve disease (MMVD) defined as characteristic valvular lesions of the mitral valve apparatus, echocardiographic

evidence of left atrial and left ventricular dilatation and radiographic evidence of cardiomegaly (vertebral heart sum (VHS) > 10.5. The median time to onset of clinical signs of heart failure or cardiac death/euthanasia was extended in these dogs by approximately 15 months. Additionally, there was a reduction in the heart size of dogs treated with pimobendan in the preclinical stage of myxomatous mitral valve disease. Furthermore, overall survival time was prolonged by approximately 170 days in all dogs receiving pimobendan independent of their cause of death (cardiac death/euthanasia and non-cardiac death/euthanasia). Cardiac related death or euthanasia occurred in 15 dogs in the pimobendan group and 12 dogs in the placebo group prior to the onset of CHF. Dogs in the pimobendan group spent a longer time in the study (347.4 patient years) than those in the placebo group (267.7 patient years) resulting in a lower rate of occurrence.

In a randomized and placebo controlled study including Doberman Pinschers with preclinical dilated cardiomyopathy (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter following echocardiographic diagnosis), the time to onset of congestive heart failure or sudden death was extended and survival time was prolonged among dogs administered pimobendan. Additionally, there was a reduction in the heart size of dogs treated with pimobendan in the preclinical stage of dilated cardiomyopathy. Efficacy evaluation is based on data from 19 (of 39) and 25 (of 37) dogs that reached the primary efficacy endpoint in the pimobendan and the placebo group, respectively.

## **5.2 Pharmacokinetic particulars**

### Absorption:

After oral administration of this veterinary medicinal product the absolute bioavailability of its active substance is 60 - 63%. Since simultaneous or previous food intake reduces the bioavailability, pimobendan should be administered about 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 demethylated by oxidation to the major active metabolite (UD-CG212). Further metabolic steps are phase II conjugates of UD-CG212, such as glucuronides and sulphates.

### Elimination:

The plasma elimination half-life of pimobendan is  $0.4 \pm 0.1$  hours, which corresponds to the high clearance of  $90 \pm 19$  ml/min/kg and the short mean residence of  $0.5 \pm 0.1$  hours.

The most significant active metabolite is eliminated with a plasma elimination half-life of  $2.0 \pm 0.3$  hours. Almost the entire dose is eliminated in the faeces.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Microcrystalline cellulose  
Starch, Pregelatinised  
Sodium starch glycolate (Type A)  
Macrogol 6000  
Stearyl macrogolglycerides  
Dried yeast  
Liver powder flavour  
Talc  
Magnesium stearate

### **6.2 Major incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life of the divided (halved) tablets after opening the immediate packaging: 3 days

### **6.4 Special precautions for storage**

Do not store above 25°C.

Divided tablets should be returned to the open blister pocket and placed back in the cardboard box.

### **6.5 Nature and composition of immediate packaging**

Heat sealed Aluminium// PVC/ Aluminium/ Polyamide blister containing 10 tablets.

Cardboard box with 2 blisters of 10 tablets (20 tablets)

Cardboard box with 5 blisters of 10 tablets (50 tablets)

Cardboard box with 10 blisters of 10 tablets (100 tablets)

Not all pack sizes 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 Vetmedica GmbH  
55216 Ingelheim/Rhein  
Germany

## **8. MARKETING AUTHORISATION NUMBER(S)**

<To be completed nationally.>

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

<To be completed nationally.>

Date of first authorisation: DD/MM/YYYY

Date of last renewal: DD/MM/YYYY

## **10. DATE OF REVISION OF THE TEXT**

<To be completed nationally.>

MM/YYYY

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vetmedin Chew 2.5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)  
Vetmedin vet. 2.5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)  
Vetmedin S 2.5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Pimobendan

**2. STATEMENT OF ACTIVE SUBSTANCES**

One chewable tablet contains:  
Pimobendan: 2.5 mg

**3. PHARMACEUTICAL FORM**

Chewable tablet.

**4. PACKAGE SIZE**

20 tablets  
50 tablets  
100 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP {month/year}

Shelf life of the divided (halved) tablets after opening the blister: 3 days.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

**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)**

<To be completed nationally.>

**17. MANUFACTURER’S BATCH NUMBER**

Batch: {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vetmedin Chew 2.5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)  
Vetmedin vet. 2.5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT,SE)  
Vetmedin S 2.5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Pimobendan

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**



**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

Vetmedin Chew 1.25 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 2.5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 10 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin vet. 1.25 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 2.5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 10 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin S 1.25 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 2.5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 10 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

### **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

55216 Ingelheim/Rhein

Germany

#### Manufacturer responsible for batch release:

Lavet Pharmaceuticals Ltd.,

Kistarcsa, 2143 Batthyány u. 6., Hungary

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vetmedin Chew 1.25 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 2.5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin Chew 10 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)

Vetmedin vet. 1.25 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 2.5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin vet. 10 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)

Vetmedin S 1.25 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 2.5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Vetmedin S 10 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Pimobendan

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

One chewable tablet contains:

Pimobendan: 1.25 mg

Pimobendan: 2.5 mg

Pimobendan: 5 mg

Pimobendan: 10 mg

Brownish, oval, divisible tablet, scored on both sides.  
The tablet can be divided into two equal parts.

#### **4. INDICATIONS**

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation).  
(See also section “Dosage, routes and method of administration”).

For the treatment of dilated cardiomyopathy in the preclinical stage (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter) in Doberman Pinschers following echocardiographic diagnosis of cardiac disease (see section “Special warnings” and “Precautions for use in animals”).

For the treatment of dogs with myxomatous mitral valve disease (MMVD) in the preclinical stage (asymptomatic with a systolic mitral murmur and evidence of increased heart size) to delay the onset of clinical symptoms of heart failure (see section “Special warnings” and “Special precautions for use in animals”).

#### **5. CONTRAINDICATIONS**

Do not use pimobendan in hypertrophic cardiomyopathies or in diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).  
Since pimobendan is metabolised mainly via the liver, it should not be used in dogs with severe impairment of liver function.  
(See also section “Pregnancy and lactation”).  
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

#### **6. ADVERSE REACTIONS**

In rare cases a slight positively chronotropic effect (rise in heart rate) and vomiting can occur. However, these effects are dose-dependent and can be avoided by reducing the dose.  
In rare cases transient diarrhoea, anorexia or lethargy have been observed.  
In rare cases, an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.  
Although a relationship with pimobendan has not been clearly established, in very rare cases, signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment. 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, 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 AND METHOD OF ADMINISTRATION**

Oral use.

Determine the bodyweight accurately before treatment to ensure correct dosage.

A dosage range of 0.2 mg to 0.6 mg pimobendan/kg body weight, divided into two doses daily, should be respected.

The preferable daily dose is 0.5 mg pimobendan/kg body weight, divided into two doses daily.

This corresponds to:

One 1.25 mg chewable tablet in the morning and one 1.25 mg chewable tablet in the evening for a body weight of 5 kg.

One 2.5 mg chewable tablet in the morning and one 2.5 mg chewable tablet in the evening for a body weight of 10 kg.

One 5 mg chewable tablet in the morning and one 5 mg chewable tablet in the evening for a body weight of 20 kg.

One 10 mg chewable tablet in the morning and one 10 mg chewable tablet in the evening for a body weight of 40 kg.

Administration of pimobendan should take place approximately one hour before feeding.

Pimobendan may also be used in combination with a diuretic, e.g. furosemide or torasemide.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Do not exceed the recommended dosage.

To allow accurate dosing according to body weight, the chewable tablet can be halved along the designated score line.

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25°C.

Divided tablets should be returned to the open blister pocket and placed back in the cardboard box.

Shelf life of the divided (halved) tablets after opening the blister: 3 days.

Do not use after the expiry date stated on the label after "EXP". The expiry date refers to the last day of the month.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

The product has not been tested in cases of asymptomatic DCM in Dobermans with atrial fibrillation or sustained ventricular tachycardia.

The product has not been tested in cases of asymptomatic myxomatous mitral valve disease in dogs with significant supraventricular and/or ventricular tachyarrhythmia.

Special precautions for use in animals:

The blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus.

For use in the preclinical stage of dilated cardiomyopathy (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter), a diagnosis should be made by means of a comprehensive cardiac examination (incl. echocardiographic examination and possibly Holter monitoring).

For use in the preclinical stage of myxomatous mitral valve disease (stage B2, according to ACVIM consensus: asymptomatic with mitral murmur  $\geq$  3/6 and cardiomegaly due to myxomatous mitral valve

disease), a diagnosis should be made by means of a comprehensive physical and cardiac examination which should include echocardiography or radiography where appropriate.

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan. (See also section “Adverse Reactions”).

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:  
Wash hands after use.

To avoid accidental ingestion of the product by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the cardboard box.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Advice to doctors: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects. However, these studies have shown evidence of maternotoxic and embryotoxic effects at high doses, and have also shown that pimobendan is excreted into milk. The safety of the product has not been assessed in pregnant or nursing bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

In pharmacological studies no interaction between the cardiac glycoside ouabain (strophanthin) and pimobendan was observed. The pimobendan-induced increase in cardiac contractility is attenuated by the calcium antagonists verapamil and diltiazem and by the  $\beta$ -antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):

An overdose may cause a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

In prolonged exposure (6 months) of healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed in some dogs. These changes are of pharmacodynamic origin.

Incompatibilities:

None known.

### **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. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

<To be completed nationally.>

### **15. OTHER INFORMATION**

Heat sealed Aluminium// PVC/ Aluminium/ Polyamide blister containing 10 tablets.

Cardboard box with 2 blisters of 10 tablets (20 tablets)

Cardboard box with 5 blisters of 10 tablets (50 tablets)

Cardboard box with 10 blisters of 10 tablets (100 tablets)

Not all pack sizes may be marketed.

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