ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin Chew 5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)
Vetmedin vet. 5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)
Vetmedin S 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 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 ≥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 β-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 20 kg, this corresponds to one 5 mg chewable tablet in the morning and one 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 benzimadazole-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 ≥ 6 years, bodyweight ≥ 4.1 and ≤ 15 kg, characteristic systolic heart murmur of moderate to high intensity (≥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 ± 0.1 hours, which corresponds to the high clearance of 90 ± 19 ml/min/kg and the short mean residence of 0.5 ± 0.1 hours.
The most significant active metabolite is eliminated with a plasma elimination half-life of 2.0 ± 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
Stearoyl 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 5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)
Vetmedin vet. 5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)
Vetmedin S 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: 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 5 mg chewable tablets for dogs (AT, BE, DE, IE, IT, LI, LU, NL, UK)
Vetmedin vet. 5 mg chewable tablets for dogs (CY, DK, EL, ES, FI, HR, IS, NO, PL, PT, SE)
Vetmedin S 5 mg chewable tablets for dogs (BG, CZ, EE, FR, HU, LT, LV, RO, SI, SK)

Pimobendan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

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 ≥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 β-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.