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

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4320

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

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
Vetmedin Chew 2.5 mg chewable tablets for dogs
Vetmedin Chew 5 mg chewable tablets for dogs
Vetmedin Chew 10 mg chewable tablets for dogs

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

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
Vetmedin Chew 2.5 mg chewable tablets for dogs
Vetmedin Chew 5 mg chewable tablets for dogs
Vetmedin Chew 10 mg chewable tablets for dogs

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

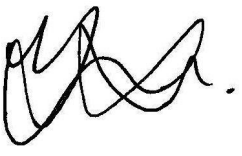
November 2019

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.



Approved: 02 March 2020