ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:
Pimobendan 1.25 mg

3. PACKAGE SIZE

50 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the bottle: 100 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep the bottle tightly closed in order to protect from moisture.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 08327/3016

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polyethylene bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:
Pimobendan 1.25 mg

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by ….

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep the bottle tightly closed in order to protect from moisture.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetmedin 1.25 mg chewable tablets for dogs

2. Composition

Each chewable tablet contains:
Pimobendan 1.25 mg
Pimobendan 2.5 mg
Pimobendan 5 mg

Oblong, scored, mottled brown tablets with fine white spots, embossed with Boehringer Ingelheim logo and P01 (1.25 mg), P02 (2.5 mg) or P03 (5 mg).

The tablet can be divided into equal parts.

3. Target species

Dogs.

4. Indications for use

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

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.

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.

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.

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

6. Special warnings

The veterinary medicinal product has not been tested in cases of asymptomatic DCM in Dobermans with atrial fibrillation or sustained ventricular tachycardia.
The veterinary medicinal 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 safe use in the target species:

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

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.
Wash hands after use.

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

Close bottle tightly with cap directly after removal of the required number of tablets.

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 veterinary medicinal 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 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:

In the case of overdose, a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension may occur. 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.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
- Vomiting[1], diarrhoea[2] - Anorexia (loss of appetite)[2], lethargy[2] - Increased heart rate[1,3], increase in mitral valve regurgitation[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
- Mucosa petechiae (small red spots on mucosa)[5], haemorrhages (subcutaneous)[5]

1 These effects are dose-dependent and can be avoided by reducing the dose.
2 Transient
3 Due to a slight positively chronotropic effect.
4 Observed during chronic pimobendan treatment in dogs with mitral valve disease.
5 A relationship with pimobendan has not been clearly established, signs disappear when the treatment is withdrawn.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.
Determine the bodyweight accurately before treatment to ensure correct dosage.

The dose should be administered and within the dose range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight, divided into two daily doses. The preferable daily dose is 0.5 mg/kg bodyweight, divided into two daily doses (0.25 mg/kg bodyweight each) approximately 12 hours apart. Each dose should be given approximately 1 hour before feeding.

This corresponds to:
One 1.25 mg chewable tablet in the morning and one 1.25 mg chewable tablet in the evening for a bodyweight of 5 kg.

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

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

Bodyweight	1.25 mg chewable tablet		2.5 mg chewable tablet		5 mg chewable tablet	
	Morning	Evening	Morning	Evening	Morning	Evening
5 kg	1	1				
10 kg			1	1		
20 kg					1	1

The veterinary medicinal product may be combined with a diuretic, e.g., furosemide.

9. Advice on correct administration

Do not exceed the recommended dosage.
Chewable tablets can be halved at the score line provided, for dosage accuracy, according to the bodyweight. Use any divided tablet at the next administration time.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the bottle tightly closed in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the bottle: 100 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08327/3016

1.25 mg:
Bottle of 50 or 100 tablets. Not all pack sizes may be marketed.

2.5 mg and 5.0 mg:
Bottle of 50 tablets.

15. Date on which the package leaflet was last revised

November 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Local representatives and contact details to report suspected adverse reactions:

17. Other information

Approved 15 March 2024