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 Chew 10 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

Pimobendan: 10 mg

3. PACKAGE SIZE

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

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Divided tablets should be returned to the open blister pocket and placed back in the cardboard box.

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 Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 61700/3026

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin Chew 10 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each chewable tablet contains:

Pimobendan: 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetmedin Chew 10 mg chewable tablets for dogs

2. Composition

Each 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 chewable tablet can be divided into two 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 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 veterinary medicinal 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 veterinary medicinal product has not been established during pregnancy and lactation in 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:
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.

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], haemorrhage[5] (subcutaneous)

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 reporting system details}.

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

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible..

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 (0.25 mg/kg bodyweight each) approximately 12 hours apart.

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.

Body weight	**1.25 mg chewable tablet**		**2.5 mg chewable tablet**		**5 mg chewable tablet**		**10 mg chewable tablet**	
	Morning	Evening	Morning	Evening	Morning	Evening	Morning	Evening
5 kg	1	1						
10 kg			1	1				
20 kg					1	1		
40 kg							1	1

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 periods

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: 3 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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 61700/3026

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Contact details to report suspected adverse reactions:
Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release:
Lavet Pharmaceuticals Ltd.,
Batthyány utca 6, Kistarcsa, 2143,
Hungary

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

Gavin Hall
Approved: 28 November 2025