LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg chewable tablets for dogs

pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains pimobendan 5 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

50 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened, use by ……
Shelf life after first opening the bottle: 100 days

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

16. MARKETING AUTHORISATION NUMBER

Vm 08327/5020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg chewable tablets for dogs

pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

pimobendan 5 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Not applicable.

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
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

16. MARKETING AUTHORISATION NUMBER

Vm 08327/5020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE "LEAFLET"

Vetmedin 5 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
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5 mg chewable tablets for dogs

Pimobendane

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

One chewable tablet contains: pimobendan 5 mg

Oval, scored, mottled brown tablets with fine white spots, embossed with Boehringer Ingelheim logo and P03.
The tablet can be divided into 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 for each species, 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 "Special 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”).

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.

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

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.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Determine the bodyweight accurately before treatment to ensure correct dosage.

The dose should be orally 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). Each dose should be given approximately 1 hour before feeding.

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

The 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.

10. WITHDRAWAL PERIOD

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
Use any divided tablet at the next administration time.

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 (see also “Other information”).

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

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 product has not been assessed in pregnant or nursing bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.

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 (symptoms, emergency procedures, antidotes)

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.

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 2023

15. OTHER INFORMATION

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 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.

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.

Pack size:
Bottle of 50 tablets

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

Approved 15 March 2024