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Vetmedin Chew 1.25 mg, 2.5mg, 5 mg and 10 mg chewable tablets for dogs (GB)

Species: Dogs

Therapeutic indication:Pharmaceuticals: Cardiovascular and respiratory preparations

Active ingredient: Pimobendan

Product: Vetmedin Chew 1.25 mg, 5 mg and 10 mg chewable tablets for dogs

Product index: Vetmedin Chew

Incorporating:

Presentation

Brownish, oval, divisible tablet, scored on both sides.

One 1.25 mg chewable tablet contains 1.25 mg pimobendan as active substance.

One 2.5 mg chewable tablet contains 2.5 mg pimobendan as active substance.

One 5 mg chewable tablet contains 5 mg pimobendan as active substance.

One 10 mg chewable tablet contains 10 mg pimobendan as active substance.

The chewable tablets can be divided into equal parts.

Uses

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation) (See section 'Dosage and 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 'Contra-indications, warnings, etc').

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 'Contra-indications, warnings, etc').

Dosage and administration

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 daily doses, should be respected.

The preferable daily dose is 0.5 mg pimobendan/kg body weight, divided into two daily doses (0.25 mg/kg bodyweight each) approximately 12 hours apart.

For a body weight of 5 kg, 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 10 kg, this corresponds to one 2.5 mg chewable tablet in the morning and one 2.5 mg chewable tablet in the evening.

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.

For a body weight of 40 kg, this corresponds to one 10 mg chewable tablet in the morning and one 10 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.

Contra-indications, warnings, etc

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.

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.

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

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 'Further Information' section).

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.

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

Adverse reactions (frequency and seriousness)

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	•Vomiting1, diarrhoea2
	•Anorexia2, lethargy2
	•Increased heart rate1,3
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	•Mucosa petechiae5, ha

1 These 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

<u>Pregnancy and lactation:</u>

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 (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.

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.

<u>Special precautions for the protection of the environment:</u>

Not applicable.

<u>Other precautions:</u>

Not applicable.

Pharmaceutical precautions

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life of the divided (halved) tablets: 3 days

Do not store above 25°C.

Divided tablets should be returned to the open blister pocket and placed back in the cardboard box.

For animal treatment only.

To be supplied only on veterinary prescription.

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product

should be disposed of in accordance with local requirements.

Legal category

Legal category:POM-V

Packaging quantities

Heat sealed Aluminium// PVC/ Aluminium/ Polyamide blister strip containing 10 tablets.

Cardboard box with 2 blister strips of 10 tablets (20 tablets)

Cardboard box with 5 blister strips of 10 tablets (50 tablets)

Cardboard box with 10 blister strips of 10 tablets (100 tablets)

Not all packs sizes may be marketed.

Marketing Authorisation Holder (if different from distributor)

Boehringer Ingelheim Animal Health UK Limited

Ellesfield Avenue

Bracknell

Berkshire

RG12 8YS

Further information

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 two action mechanisms: 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 veterinary medicinal 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 veterinary medicinal 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.

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.

Marketing Authorisation Number

Vetmedin Chew 1.25 mg chewable tablets for dogs: Vm 08327/5031

Vetmedin Chew 2.5 mg chewable tablets for dogs: Vm 08327/5032

Vetmedin Chew 5 mg chewable tablets for dogs: Vm 08327/5033

Vetmedin Chew 10 mg chewable tablets for dogs: Vm 08327/5034

Significant changes

GTIN

GTIN description: Vetmedin Chew 1.25 mg chewable tablets for dogs x 50

GTIN:5012917025378

GTIN description: Vetmedin Chew 1.25 mg chewable tablets for dogs x 100

GTIN:5012917025385

GTIN description: Vetmedin Chew 5 mg chewable tablets for dogs x 50

GTIN:5012917025347

GTIN description: Vetmedin Chew 10 mg chewable tablets for dogs x 50

GTIN:5012917025354