

Vetmedin® Chew

Vetmedin Chew 1.25 mg chewable tablets for dogs

Vetmedin Chew 5 mg chewable tablets for dogs

Vetmedin Chew 10 mg chewable tablets for dogs

Marketing authorisation holder

Boehringer Ingelheim Ltd

Ellesfield Ave, Bracknell, Berks, RG12 8YS. UK

Manufacturer responsible for batch release:

Lavet Pharmaceuticals Ltd.,

Kistarcsa, 2143 Batthyány u. 6., Hungary

Active substance

One chewable tablet contains:

Pimobendan: 1.25 mg

Pimobendan: 5 mg

Pimobendan: 10 mg

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

The tablet can be divided into equal halves.

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 the section "Special warnings" and "Precautions for use in animals"). The tablets can be divided into equal halves.

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").

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 These signs disappear when the treatment is withdrawn.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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species

Dog

Dosage, route and method of administration

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 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. Pimobendan is orally administered. Administration of pimobendan should take place approximately one hour before feeding. Pimobendan may also be used in combination with a diuretic, e.g. furosemide.

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 scoreline.

Withdrawal period

Not applicable.

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. The 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.

Special warnings

The product has not been tested in cases of asymptomatic DCM in Dobermans with

atrial fibrillation or sustained ventricular tachycardia.

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 endsystolic and end-diastolic diameter), a diagnosis should be made by means of a comprehensive cardiac examination (incl. echocardiographic examination and possibly Holter monitoring).

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

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.

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 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 was observed in some dogs. These changes are of pharmacodynamic origin.

Incompatibilities

None known.

Disposal of unused product or waste materials

Any unused veterinary medicinal product or waste materials derived from such

veterinary medicinal products should be disposed of in accordance with national requirements.

Date on which the package leaflet was last approved

12/2015