Dosage Chart

Recommended dosage based on the dogs body weight,
to be taken twice daily and at least one hour before feeding.

Body Weight	Daily dose at 0.5 mg/kg	B.I.D. Dose	Morning Tablet	Evening Tablet
5 kg	2.5 mg	1.25 mg		
10 kg	5 mg	2.5 mg		
15 kg	7.5 mg	3.75 mg		
20 kg	10 mg	5 mg		
25 kg	12.5 mg	6.25 mg		
30 kg	15 mg	7.5 mg		
35 kg	17.5 mg	8.75 mg		
40 kg	20 mg	10 mg		
50 kg	25 mg	12.5 mg		
60 kg	30 mg	15 mg		

The dose range is 0.2-0.6 mg/kg body weight per day with the preferable dose being 0.5 mg/kg body weight per day divided into two doses.

Cardisure®
Pimobendan

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Cardisure Flavoured 1.25 / 2.5 / 5 / 10 mg tablets for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Pimobendan
Each tablet contains 1.25 / 2.5 / 5 / 10 mg pimobendan.
Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Tablet
Light brown round tablets, scored on one side and plain on the other side
The 1.25 mg tablets can be divided into 2 equal parts.
The 2.5 / 5 / 10 mg tablets can be divided into 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species
Dogs.

4.2 Indications for use, specifying the target species
For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

4.3 Contraindications
Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).

See also section 4.7.

4.4 Special warnings
The product should be administered on an empty stomach at least one hour before meals, as absorption is reduced when given with feed.

4.5 Special precautions for use
(i) Special precautions for use in animals

The product is flavoured. To avoid accidental ingestion the tablets should be stored out of reach of dogs. An in vitro study in rat tissue demonstrated that pimobendan increased glucose-induced insulin release from pancreatic ß-cells in a dose dependent manner. If the product is administered to diabetic dogs, blood glucose levels should be carefully monitored. As pimobendan is metabolised in the liver, particular care should be taken when administering the product to dogs with severe hepatic insufficiency.

(ii) 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.

4.6 Adverse reactions (frequency and seriousness)
A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and may be avoided by reducing the dose in these cases. 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. Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.

4.7 Use during pregnancy, lactation or lay
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.

4.8 Interaction with other medicinal products and other forms of interaction
In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the ß-antagonist propranolol.

4.9 Amounts to be administered and administration route
The preferable daily dose is 0.5 mg pimobendan/kg body weight.
Do not exceed the recommended dosage.
Determine the bodyweight accurately before treatment to ensure correct dosage.

The tablets should be administered orally at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The dose should be divided into two administrations (0.25 mg/kg body weight each), one half of the dose in the morning and the other half approximately 12 hours later. The maintenance dose should be individually adjusted by the responsible veterinarian according to the severity of the disease.

The product may be combined with a diuretic treatment e.g. furosemide.
To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half. To break a double scored tablet into quarters, place the tablet on an even surface with the scored side up and apply pressure on the middle with your thumb. Each dose should be given approximately one hour before feeding.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
In the case of overdose, a positive chronotropic effect and vomiting may occur. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.

4.11 Withdrawal period(s)
Not applicable.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Cardiac stimulant (phosphodiesterase inhibitor)
ATCvet code: QC01CE90

5.1 Pharmacodynamic properties
Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.
Pimobendan exerts its stimulatory myocardial effect by a dual mode of action: it increases calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through inhibition of phosphodiesterase III activity.

When used in cases of 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 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.

5.2 Pharmacokinetic particulars
Absorption:
Following oral administration of this veterinary medicinal product the absolute bio-availability of the active principle is 60 - 63%. Since this bio-availability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 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 oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II conjugates of UD-CG 212, in essence glucuronides and sulphates.

Elimination
The plasma elimination half-life of pimobendan is 1.1 ± 0.7 hours.

The main active metabolite is eliminated with a plasma elimination half-life of 1.5 ± 0.2 hours. Almost the entire dose is eliminated via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Cellulose, microcrystalline (E460)
Croscarmellose sodium
Magnesium stearate
Natural meat flavour

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale : 30 months.
Shelf life of divided tablets after first opening the blister: 3 days

6.4. Special precautions for storage
Return any divided tablet to the opened blister and use within 3 days.
Do not store above 30°C

6.5 Nature and composition of immediate packaging
Aluminium – PVC/PE/PVDC blister:
10 tablets per blister: 2, 5, 10 or 25 blisters per carton.

Aluminium – Aluminium blister:
10 tablets per blister: 2, 5, 10 or 25 blisters per carton.

Not all presentations may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands
Tel: + 31 497 544300, Fax: + 31 497 544302

8. MARKETING AUTHORISATION NUMBER(S)
Cardisure 1.25 mg tablet Vm 16849/4026
Cardisure 2.5 mg tablet Vm 16849/4027
Cardisure 5 mg tablet Vm 16849/4028
Cardisure 10 mg tablet Vm 16849/4029

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
9 August 2011

10 DATE OF REVISION OF THE TEXT
August 2011

Cardisure is a UK: POM-V IE: POM
Use medicines responsibly: www.noah.co.uk/responsible

[1]Atkins et al (2009) ACVIM consensus statement: guidelines for the diagnosis and treatment of chronic valvular heart disease. Journal of Veterinary Internal Medicine 23: 1142-1150

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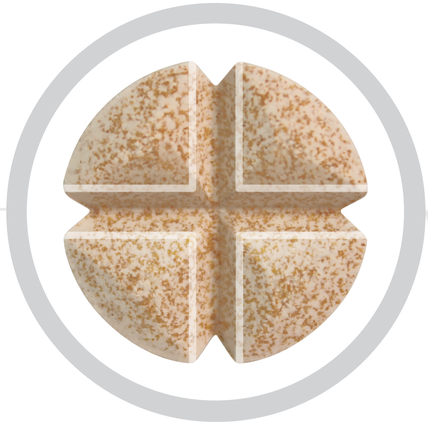
Cardisure®
Pimobendan



Pimobendan
plus added benefits

Dechra
Veterinary Products

Cardisure®
Pimobendan

Pimobendan *plus added benefits*

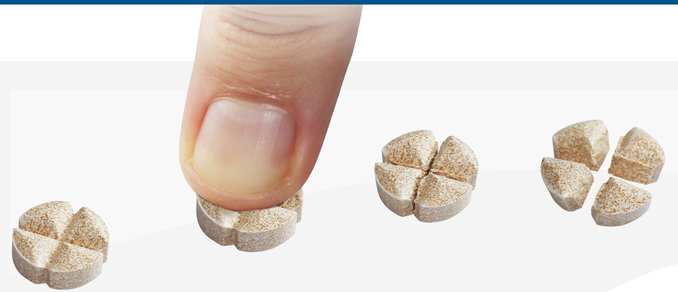
Cardisure is bioequivalent to the leading brand while also offering added benefits. The flavoured, divisible, blister-packed tablets are available in four strengths and enable accurate and flexible dosing.

Treatment with pimobendan at the onset of clinical signs of congestive heart failure is recommended in guidelines published by the American College of Veterinary Internal Medicine.[1]

Its dual actions are:

- Positive inotropy (mediated by sensitisation of myocardial fibres to intracellular calcium and by phosphodiesterase III inhibition) for improved contractility without increasing myocardial oxygen demand
- Vasodilation (mediated by phosphodiesterase III inhibition) for reduced preload and afterload, easing the workload of the failing heart

With the further plus of competitive pricing, why not contact us today and discover how using Cardisure can add up for your practice.



Divisible tablets

Cardisure's easily divisible tablets enable accurate and flexible dosing.

Blister packs

Cardisure comes in blister packs which are quick and easy to dispense.

Each box holds 10 strips of 10 tablets and divided tablets can be used up to three days after first opening the blister pack.

Flavoured tablets

Cardisure tablets have a natural meat flavouring to encourage acceptance.

4 strengths

Flexible dosing for dogs of all sizes.