Cardisure® Flavoured

1.25 mg / 2.5 mg / 5 mg / 10 mg Tablets for dogs

UK IE

Marketing authorisation holder:
Eurovet Animal Health BV,
Handelsweg 25,
5531 AE Bladel,
The Netherlands

Manufacturer responsible for batch release:
Dales Pharmaceuticals Limited,
Snaygill Industrial Estate,
Keighley Road, Skipton,
North Yorkshire, BD23 2RW, UK

Distributor:
Dechra Veterinary Products Limited,
Sansaw Business Park, Hadnall,
Shrewsbury, Shropshire, SY4 4AS, UK

Name of the veterinary medicinal product:

Cardisure Flavoured 1.25 mg tablets for dogs, Pimobendan.

Cardisure Flavoured 2.5 mg tablets for dogs, Pimobendan.

Cardisure Flavoured 5 mg tablets for dogs, Pimobendan.

Cardisure Flavoured 10 mg tablets for dogs, Pimobendan.

Statement of the active substance and other ingredients:

Active substance: Pimobendan

Cardisure 1.25 mg: Each tablet contains 1.25 mg pimobendan.

Cardisure 2.5 mg: Each tablet contains 2.5 mg pimobendan.

Cardisure 5 mg: Each tablet contains 5 mg pimobendan.

Cardisure 10 mg: Each tablet contains 10 mg pimobendan.

Indications: For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

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).

Adverse reactions: 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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Although a relationship with pimobendan has not been clearly established, in very rare cases, effects on primary haemostasis (petechia on mucous membranes, subcutaneous haemorrhage) 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 These signs disappear when the treatment is withdrawn.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.

Target species: Dogs.

Dosage for each species, route and method of administration: 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 preferable daily dose is 0.5 mg pimobendan/kg body weight. 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 according to the severity of the disease.

Table to show dosing guide

Daily Pimobendan Dosage
0.2 - 0.6 mg/kg. The preferable daily dose is 0.5 mg/kg

		No. of tablets per administration							
		Morning				Evening			
Body Weight (kg)	Daily Dosage (mg)	1.25 mg	2.5 mg	5 mg	10 mg	1.25 mg	2.5 mg	5 mg	10mg
< 5	1.25	½	-	-	-	½	-	-	-
5 - 10	2.5	1	-	-	-	1	-	-	-
10 - 20	5	-	1	-	-	-	1	-	-
21 - 40	10	-	-	1	-	-	-	1	-
41 - 60	20	-	-	-	1	-	-	-	1
> 60	30	-	-	-	½	-	-	-	1 ½

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.

Advice on correct administration:
This product should be used only in dogs with cardiac insufficiency. Do not exceed the recommended dosage. Determine the bodyweight accurately before treatment to ensure correct dosage.

Withdrawal period: Not applicable.

Special storage precautions: Keep out of the sight and reach of children. Do not store above 30°C. Return any divided tablet to the opened blister and use within 3 days. Keep the blisters in the outer carton.

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.

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 β-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.

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.

Use during pregnancy, lactation or lay: Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic effects. However, these studies have shown evidence of maternotoxic effects and they have 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 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 β-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes): 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.

Special precautions for the disposal of unused product or waste materials: Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon/pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved: 13/05/2014

Other information: 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.

Cardisure 1.25 mg tablets:

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.

Cardisure 2.5 mg tablets:

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.

Cardisure 5 mg tablets:

Aluminium - PVC/PE/PVDC blister: 10 tablets per blister: 2, 5, 10 or 25 blisters per carton. Aluminium - Aluminium blister: 5 tablets per blister: 4, 10, 20 or 50 blisters per carton.

Cardisure 10 mg tablets:

Aluminium - PVC/PE/PVDC blister: 10 tablets per blister: 2, 5, 10 or 25 blisters per carton. Aluminium - Aluminium blister: 5 tablets per blister: 4, 10, 20 or 50 blisters per carton.

Not all pack sizes may be marketed.

For animal treatment only.

UK only:
Cardisure 1.25 mg tablets: Vm: 16849/4026
Cardisure 2.5 mg tablets: Vm: 16849/4027
Cardisure 5 mg tablets: Vm: 16849/4028
Cardisure 10 mg tablets: Vm: 16849/4029
POM-V
Prescription Only Medicine - Veterinarian

IE only:
Cardisure 1.25 mg tablets: VPA: 10989/059/001
Cardisure 2.5 mg tablets: VPA: 10989/059/002
Cardisure 5 mg tablets: VPA: 10989/059/003
Cardisure10 mg tablets: VPA: 10989/059/004
POM
Prescription Only Medicine

Veterinary medicinal product authorised for use in UK and Ireland.

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

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Divisible Tablet