

Product Name:	Cardisure Oral Solution
APVMA Approval No:	84375/110276

Label Name:	Cardisure Oral Solution
Signal Headings:	PRESCRIPTION ANIMAL REMEDY
	KEEP OUT OF REACH OF CHILDREN
	FOR ANIMAL TREATMENT ONLY
	READ SAFETY DIRECTIONS

Constituent Statements:	1.5 mg/mL PIMOBENDAN
----------------------------	----------------------

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

Net Contents:	25 mL

Directions for Use:	Read the enclosed leaflet before using this product

Restraints:			
-------------	--	--	--

Contraindications:	This product is contraindicated for 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).

Precautions:	Cardisure Oral Solution should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.
	Studies into the effect of pimobendan on the reproductive function of male doges have not been conducted.
	The use in dogs not showing signs of cardiac disease is not recommended.
	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 B-antagonist propranolol.
--	---

Side Effects:	A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and can be avoided by reducing the dose in those cases. In rare cases transient diarrhoea, anorexia or lethargy have been observed.
	in the cases transient diarnoca, anorexia of lethalgy have been observed.

Dosage and Administration:	Shake well before use.
	Cardisure Oral Solution should be administered orally at a dose range of 0.1 mg to 0.3 mg pimobendan/kg bodyweight twice daily. The ideal dose is 0.25 mg pimobendan/kg body weight (equivalent to 0.167 mL Cardisure Oral Solution/kg bodyweight) twice daily administered approximately 12 hours apart. Each dose should be given approximately one hour before feeding.
	Dosing procedure using the measuring syringe: Shake the bottle. Unscrew the bottle cap and attach the dosing syringe to the bottle by gently pushing the syringe end into the insert at the top of the bottle to ensure a good seal. Invert the bottle and draw an accurate volume of the product. Dispense the dose by depressing the syringe in the mouth of the animal over the base of the tongue. The syringe can be reused. Rinse the syringe after each use.

General Directions:	Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimentic, non- glycoside inotropic substance with potent vasodilatative properties.
	Cardisure Oral Solution may be given concurrently with diuretic treatment such as furosemide.
	In the case of overdosing, symptomatic treatment should be initiated.
	Action
	<ul> <li>Pimobendan exerts its stimulatory myocardial effect by a dual mechanism of action:</li> <li>increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase</li> <li>(type III). It also exhibits a vasodilating action through an inhibitory action on</li> <li>phosphodiesterase III activity. Following oral administration of pimobendan the absolute</li> <li>bioavailability of the active principal is 60-63%.</li> <li>The mean plasma protein binding is 93%. The plasma elimination half-life of pimobendan</li> <li>is approximately 30 minutes and the main active metabolite elimination half-life is</li> <li>approximately 2 hours. Almost the entire dose is eliminated via faeces.</li> </ul>
	Use during pregnancy and lactation
	In studies with rats and rabbits pimobendan had no effect on fertility and embryotoxic effects only occurred at maternotoxic doses. In rat experiments it has been shown that pimobendan is excreted in milk.

Withholding Periods:	
Trade Advice:	

Safety Directions:	Wash hands after use.
First Aid Instructions:	If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131

126

First Aid Warnings:	
Additional User Safety:	
Environmental Statements:	
Disposal:	Dispose of empty container by wrapping with paper and putting in garbage.

Store below 30  $^\circ\text{C}$  (room temperature). Protect from light. Do not freeze.

Storage: