RLP
APPROVED

Product Name: CORMEDIN 2.5 MG TABLETS FOR DOGS

APVMA Approval No: 83489/136485

Label Name:	CORMEDIN 2.5 MG TABLETS FOR DOGS

Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY

Constituent Statements:	Each tablet contains 2.5 mg PIMOBENDAN

Claims:	CORMEDIN 2.5 MG TABLETS FOR DOGS are indicated for: The treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation). The treatment of preclinical DCM in large breeds. When used in cases of preclinical DCM in large breed dogs, pimobendan significantly prolonged the time to onset of CHF or sudden death, and also resulted in prolongation of the time to death due to all causes. Doberman Pinscher dogs with preclinical DCM treated with pimobendan also demonstrated a significant reduction in Left Ventricular Internal Diameter in both systole and diastole (LVIDs/d) in response to therapy.

Net Contents:	14 tablets 28 tablets 42 tablets 56 tablets 84 tablets 112 tablets

Directions for Use:	

Restraints:	

Contraindications:	This product is contraindicated for use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not recommended for functional or anatomical reasons (e.g. aortic stenosis).

Precautions:	CORMEDIN TABLETS FOR DOGS 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 dogs have not been conducted. 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.

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.

Dosage and Administration:	CORMEDIN TABLETS FOR DOGS should be administered orally at a dose range of 0.1 - 0.3 mg pimobendan/kg bodyweight twice daily. The ideal dose is 0.25 mg pimobendan/kg bodyweight twice daily administered 12 hours apart. Each dose should be given on an empty stomach, and at least one hour before feeding. An example of the number and tablet size to be administered for a dog within weight bands is given below. However, the veterinarian may choose the dose within the recommended dose range which is appropriate for their patient. This section contains file attachment.

General Directions:	Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilative properties. Each CORMEDIN 2.5 MG TABLETS FOR DOGS palatable tablet contains 2.5 mg pimobendan. CORMEDIN TABLETS FOR DOGS may be combined with a diuretic treatment such as furosemide. In the case of overdosing, symptomatic treatment should be initiated. Action Pimobendan exerts its stimulatory myocardial effect by a dual mechanism of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (type III). It also exhibits a vasodilating action through an inhibitory action on phosphodiesterase III activity. Following oral administration of pimobendan, the absolute bioavailability of the active principle is 60 – 63%. The mean plasma protein binding is 93%. The plasma elimination half-life of pimobendan is approximately 30 minutes and the main active metabolite elimination half-life is approximately 2 hours. Almost the entire dose is eliminated via faeces. 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:	

First Aid Instructions:	If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

First Aid Warnings:	

Additional User Safety:	

Environmental Statements:	

Disposal:	Dispose of container by wrapping with paper and putting in garbage.

Storage:	Store below 25°C (air conditioning). Keep container tightly closed.

Body-weight (kg)	**Pimobendan dosage 0.2 – 0.6 mg / kg daily divided into two treatments given in the morning and in the evening**					
	No. of tablets per administration					
	Morning			**Evening**		
	1.25 mg	**2.5 mg**	**5 mg**	**1.25 mg**	**2.5 mg**	**5 mg**
5 – 10	**1**	-	-	**1**	-	-
>10 – 20	-	**1**	-	-	**1**	
>20 – 40	-	**2**	-	-	**2**	-
(select either row)	-	-	**1**	-	-	**1**
>40 - 60	-	-	**2**	-	-	**2**
>60 - 80	-	-	**3**	-	-	**3**
>80	-	-	**4**	-	-	**4**