RLP APPROVED

Company Name: **JUROX PTY LIMITED**

Product Name: **VETACE 5 MG TABLETS FOR DOGS AND CATS**

APVMA Approval No: **61920/100909**

DISPLAYED BY INFOPEST

Label Name:	VETACE 5 MG TABLETS FOR DOGS AND CATS

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

Constituent Statements:	Each tablet contains 5 mg BENAZEPRIL HYDROCHLORIDE

Claims:	For use by or under direction of a registered veterinarian. For the treatment of heart failure in dogs due to mitral regurgitation (endocardiosis) and dilated cardiomyopathy. For the treatment of hypertrophic cardiomyopathy in cats. For the treatment of chronic renal insufficiency in cats.

Net Contents:	14 tablets 28 tablets 42 tablets 56 tablets 70 tablets 84 tablets 98 tablets 112 tablets

Directions for Use:	Use as directed by prescribing veterinarian. DIRECTIONS FOR USE: READ THE ATTACHED LEAFLET BEFORE USING THIS PRODUCT

Restraints:	

Contraindications:	

Precautions:	Dogs

	Use during pregnancy and lactation: The safety of benazepril HCl has not been tested in breeding dogs. VetACE is therefore not recommended for use in pregnant or lactating bitches. No data are available in lactating bitches. In double blind clinical trials, benazepril HCl was well tolerated with an incidence of adverse effects statistically lower than observed in placebo treated dogs. A small number of dogs may exhibit transient signs of fatigue. Clinical trials have shown benazepril HCl to have good renal tolerance. Plasma urea and creatinine concentrations did not change and no evidence of renal toxicity of benazepril HCl has been observed in dogs during clinical trials. The biliary excretion of benazeprilat means that there is little risk of bioaccumulation in dogs and cats with impaired renal function. However, as is routine in cases of renal insufficiency, it is recommended to monitor plasma urea and creatinine levels. Interactions with potassium preserving drugs, like spironolactone, triamterene or amiloride cannot be ruled out. It is recommended to monitor plasma potassium levels when using VetACE in combination with a potassium sparing diuretic. As with other ACE inhibitors, the use of hypotensive medicinal products or anaesthetics with a hypotensive effect may add to the antihypertensive effect of benazepril. Cats VetACE may increase plasma creatinine concentrations at the start of therapy. This effect is related to the therapeutic effect of the product in reducing glomerular capillary blood pressure and therefore it is not necessarily a reason to stop therapy in the absence of other signs. Benazepril HCl reduced erythrocyte counts in normal cats at high doses, but this effect was not observed at the recommended dose during clinical trials in cats with chronic renal insufficiency. Therefore, as is routine in cases of chronic renal insufficiency, it is recommended to monitor plasma creatinine and erythrocyte counts during therapy. The efficacy and safety of VetACE has not been established in cats below 2.5 kg bodyweight. The safety of benazepril HCl has not been tested in breeding cats, or pregnant or lactating queens. VetACE should therefore be used only if justified clinically, considering the risk / benefit ratio. Benazepril HCl reduced ovary / oviduct weights when administered daily at 10 mg / kg for 52 weeks. ACE inhibitors have been found to be teratogenic in the second and third trimesters in other species. There are no known interactions between VetACE and other medicaments in cats. The combination of ACE inhibitors and other antihypertensive agents (e.g. calcium channel blockers, beta-blockers or diuretics) may lead to additive hypotensive effects. In man, the combination of ACE inhibitors and NSAIDs can lead to reduced antihypertensive efficacy of the ACE inhibitor or impaired renal function. Benazepril HCl has been shown to be effective and safe when used in combination with diets containing low amounts of protein and salt. ACE inhibitors may increase blood potassium levels, which may be beneficial where hypokalaemia occurs associated with chronic renal insufficiency. It is recommended to monitor plasma potassium levels when using VetACE in combinations with diuretics that may have additive potassium sparing effects.

Side Effects:	Overdose: Benazepril HCl is well tolerated by the target species. In normal dogs overdosage up to 200 fold was without incident. Transient reversible hypotension may occur in cases of accidental overdosage. Therapy should consist of intravenous infusion of warm isotonic saline solution. Signs of hypotension, such as

	tiredness or dizziness may appear in rare cases. Reduce the dose of the diuretic if necessary. In normal cats, overdosage of 10 times for one year was asymptomatic. Transient reversible hypotension may occur in cases of accidental overdosage. Therapy should consist of intravenous infusion of warm isotonic saline.

Dosage and Administration:	Oral doses to be administered once daily, with or without food: Dogs: 0.25 - 0.5 mg / kg bodyweight. Cats: 0.5 mg / kg bodyweight. Dose: 5 - 10 kg dogs: Half tablet / day 11 - 20 kg dogs: 1 tablet / day 2.5 - 5 kg cats: Half tablet / day > 5 - 10 kg cats: 1 tablet / day Heart failure in dogs: The minimum recommended oral dose is 0.25 mg / kg bodyweight, given according to the following regime:- VetACE 2.5 VetACE 5 VetACE 20 Weight of dog (kg) Standard dose Standard dose Standard dose 2.5 - 5 Half tablet > 5 - 10 1 tablet Half tablet 11 - 20 1 tablet 21 - 40 Half tablet 41 - 80 1 tablet The above dose may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon. Chronic renal insufficiency and hypertrophic cardiomyopathy in cats: The minimum recommended oral daily dose is 0.5 mg / kg bodyweight, given according to the following regime: Weight of cat (kg) VetACE 2.5 VetACE 5 2.5 - 5 1 tablet Half tablet > 5 - 10 2 tablets 1 tablet

General Directions:	Indications: VetACE is indicated for the treatment of heart failure in dogs, and chronic renal insufficiency and hypertrophic cardiomyopathy in cats. Dogs: VetACE is indicated for the treatment of left-sided heart failure in dogs, most commonly resulting from mitral regurgitation (MR) (endocardiosis) and dilated cardiomyopathy (DCM). VetACE, by inhibiting the renin angiotensin aldosterone (RAA) system, minimises the undesirable effects of vasoconstriction and sodium retention mediated by this system. The end result is an improvement in the clinical status of the dog. VetACE leads to an extension of the life span of dogs with heart failure and also improves clinical signs, notably reduction in coughing, and improvement to the quality of life. VetACE may be used in combination therapy with diuretics, for example frusemide, digoxin and antiarrhythmic drugs as necessary. Cats: VetACE is indicated for the treatment of chronic renal insufficiency in cats. In such cats, VetACE reduces protein loss in urine and lowers systemic and intraglomerular blood pressure. VetACE increases quality of life, particularly in advanced cases. VetACE increases the survival time in cats with a urinary protein / creatinine ratio (UPC) equal to or exceeding 0.8 before treatment, and improves the appetite in cats with a UPC ratio exceeding 1.0. VetACE has some beneficial effects on clinical signs and cardiac

	remodelling in cats with feline hypertrophic cardiomyopathy (HCM) and is well tolerated. Most cases of HCM in cats will require other medications in addition to VetACE. The most commonly prescribed of these medications will be a calcium channel blocker, for example diltiazem. Pharmacological properties VetACE contains benazepril hydrochloride, a prodrug hydrolysed in vivo to benazeprilat, which inhibits the angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I into active angiotensin II. VetACE reduces all effects mediated by angiotensin II, including vasoconstriction of both arteries and veins and retention of sodium and water by the kidney. VetACE causes long-lasting inhibition of plasma ACE in dogs and cats, with significant inhibition persisting for 24 hours after a single dose. Benazepril is rapidly but incompletely absorbed from the gastrointestinal tract following oral administration. Absorbed benazepril is partially hydrolysed by hepatic enzymes to the active substance, benazeprilat; unchanged benazepril and hydrophilic metabolites account for the remainder. Peak plasma benazeprilat concentrations are attained within about two hours both in fasting and fed situations. Benazepril and benazeprilat are bound to plasma proteins, and in tissues are found mainly in the liver and kidney. The major part of benazeprilat is rapidly eliminated, although there is in addition a slow terminal elimination phase. Benazeprilat is excreted approximately equally via both biliary and urinary routes in dogs, and primarily via the biliary route in cats. Repeated administration of VetACE leads to slight accumulation of benazeprilat in plasma; steady state is attained within four days. As it is excreted via the biliary route, there is little risk of bioaccumulation of benazeprilat in dogs or cats with impaired renal function. For this reason, no dose adjustment of VetACE is necessary in cases of renal insufficiency.

Withholding Periods:	

Trade Advice:	

Safety Directions:	

First Aid Instructions:	FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 13 1126, New Zealand 0800 764766. Additional information is listed in the Safety Data Sheet.

First Aid Warnings:	

Additional User Safety:	

Environmental Statements:	

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

Storage:	Store below 25 degrees C (Air Conditioning). Protect from heat and moisture. Unused half tablets should be returned to the open blister space and inserted back into the carton.