



**Company Name:** JUROX PTY LIMITED  
**Product Name:** VETACE 20MG TABLETS FOR DOGS  
**APVMA Approval No:** 61583/100850



<b>Label Name:</b>	VETACE 20MG TABLETS FOR DOGS
--------------------	------------------------------

<b>Signal Headings:</b>	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
-------------------------	--

<b>Constituent Statements:</b>	Each tablet contains 20 mg BENAZEPRIL HYDROCHLORIDE.
--------------------------------	--

<b>Claims:</b>	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.
----------------	---

<b>Net Contents:</b>	14 Tablets 28 Tablets 42 Tablets 56 Tablets 70 Tablets 84 Tablets 98 Tablets 112 Tablets
----------------------	---

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

<b>Restraints:</b>	
--------------------	--

<b>Contraindications:</b>	
---------------------------	--

<b>Precautions:</b>	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.
---------------------	--

	<p>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.</p> <p>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.</p> <p>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.</p>
--	---

<b>Side Effects:</b>	<p><b>Overdose:</b></p> <p>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.</p>
----------------------	---

<b>Dosage and Administration:</b>	<p>The recommended dose is 0.25 to 0.5 mg / kg administered orally once daily, with or without food.</p> <p><b>Dose:</b>  21 - 40 kg dogs: Half tablet / day  41 - 80 kg dogs: 1 tablet / day</p> <p><b>Heart failure in dogs:</b>  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  &gt; 5 - 10 1 tablet Half tablet  11 - 20 1 tablet  21 - 40 Half tablet  41 - 80 1 tablet</p> <p>The above dose may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon.</p>
-----------------------------------	---

<b>General Directions:</b>	<p><b>Indications:</b>  VetACE is indicated for the treatment of heart failure in dogs.</p> <p><b>Dogs:</b>  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</p>
----------------------------	--

combination therapy with diuretics, for example frusemide, digoxin and antiarrhythmic drugs as necessary.

**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, 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. 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 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.