

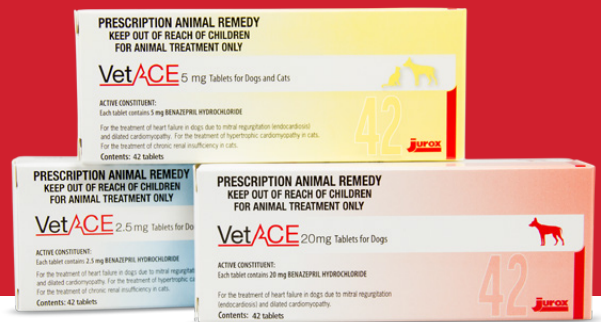


TECHNICAL NOTES



VetACE[®]

Tablets



Active Constituents

Benazepril hydrochloride 2.5, 5, 20 mg/tablet.

Actions

Pharmacology

Benazepril hydrochloride is a prodrug which is hydrolysed *in vivo* to benazeprilat, which inhibits the angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I into active angiotensin II. Benazepril hydrochloride reduces all effects mediated by angiotensin II, including vasoconstriction of both arteries and veins and retention of sodium and water by the kidney. It causes long lasting inhibition of plasma ACE in dogs and cats, with significant inhibition persisting for 24 hours after a single dose. ACE inhibitors may increase blood potassium levels, which may be beneficial when hypokalaemia associated with chronic renal insufficiency in cats occurs.

Pharmacokinetics

Benazepril hydrochloride 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 benazepril hydrochloride leads to slight accumulation of benazeprilat in plasma, and 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 the product is necessary in cases of renal insufficiency.





Indications

VetACE is indicated for the treatment of heart failure in dogs, and chronic renal insufficiency and hypertrophic cardiomyopathy in cats.

Dogs

Treatment of left sided heart failure in dogs, most commonly resulting from mitral regurgitation (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. VetACE leads to an extension of the life span of dogs with heart failure and also improves clinical signs, notably a reduction in coughing, and improvement to the quality of life. VetACE may be used in combination therapy with diuretics, for example furosemide, digoxin and antiarrhythmic drugs as necessary.

Cats

VetACE is indicated for the treatment of chronic renal insufficiency in cats. In such cats, it reduces protein loss in urine and lowers systemic and intraglomerular blood pressure. It 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. It 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 additional medications of which the most commonly prescribed will be a calcium channel blocker, for example diltiazem.

Contraindications and Precautions

Dogs

Clinical trials have shown benazepril hydrochloride to have good renal tolerance. Plasma urea and creatinine concentrations did not change and no evidence of renal toxicity of benazepril hydrochloride 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.

Use during pregnancy and lactation: The safety of benazepril hydrochloride has not been tested in breeding dogs; therefore use is not recommended in pregnant or lactating bitches. No data are available in lactating bitches.

Cats

Plasma creatinine concentrations may increase 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 hydrochloride 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. Efficacy and safety has not been established in cats below 2.5 kg bodyweight.

Use during pregnancy and lactation: The safety of benazepril hydrochloride has not been tested in breeding cats, or pregnant or lactating queens, therefore use only if justified clinically, considering the risk/benefit ratio. Benazepril hydrochloride reduced ovary and 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.



Dosage and Administration

VetACE should be given orally, once daily, with or without food.

Heart failure in dogs

The minimum recommended oral dose is 0.25 mg / kg bodyweight, given according to the following regime:-

	VetACE 2.5 mg	VetACE 5 mg	VetACE 20 mg
Weight of dog (kg)	Standard dose	Standard dose	Standard dose
2.5 - 5	½ tablet		
> 5 – 10	1 tablet	½ tablet	
11 – 20		1 tablet	
21 – 40			½ 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 mg	VetACE 5 mg
2.5 – 5	1 tablet	½ tablet
> 5 – 10	2 tablets	1 tablet

Adverse Reactions

Dogs

In double blind clinical trials, benazepril hydrochloride 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.

Overdosage

Dogs

Benazepril hydrochloride is well tolerated, with overdosage up to 200 fold being without incident in normal dogs. 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.

Cats

Benazepril hydrochloride is well tolerated, with overdosage of 10 times for one year being asymptomatic in normal cats. Transient reversible hypotension may occur in cases of accidental overdosage. Therapy should consist of intravenous infusion of warm isotonic saline.





TECHNICAL NOTES



First Aid

If poisoning occurs, contact a doctor or Poisons Information Centre on 13 1126.

GHS Information

For GHS Information see Safety Data Sheet

Presentation

Tablets (round, brown, half-scored), 2.5 mg, 5 mg, 20 mg: 42s, 28s

Storage

Store below 25°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.

Poisons Schedule

S4.

Registration Numbers

APVMA: 61589 (2.5 mg), 61920 (5 mg), 61583 (20 mg)

AU - Tech Note - VetACE / Dec 2016 / APPROVED



www.jurox.com.au
Customer Service 1800 023 312
® Registered Trademark of Jurox Pty Ltd

AUSTRALIA'S
ANIMAL HEALTH COMPANY

