For the use of Registered Veterinary Practitioner, Hospital or Laboratory

ACEPTOR®

(Benazepril hydrochloride)

COMPOSITION:

ACEPTOR® 2.5

Benazepril hydrochloride IP	
Eq. to Benazepril	2.5 mg
Excipients	q.s.

ACEPTOR® 5

Benazepril hydrochloride IP	
Eq. to Benazepril	5 mg
Excipients	q.s.

ACEPTOR® 10

Benazepril hydrochloride IP	
Eq. to Benazepril	10 mg
Excipients	q.s.

Description: Benazepril hydrochloride is a white to off-white crystalline powder, soluble (>100 mg/mL) in water, in ethanol, and in methanol.

Its empirical formula is C24H28N2O5•HCl. Benazeprilat, the active metabolite of benazepril, is a non-sulfhydryl angiotensin-converting enzyme inhibitor.

ACEPTOR® is supplied as tablets containing 5 mg and 10 mg of benazepril hydrochloride for oral administration.

Chemistry: Benazepril 3-[[1-(ethoxy-carbonyl)-3phenyl-(1S)-propyl]amino]-2,3,4,5-tetrahydro-2-oxo-1*H*-1-(3S)-benzazepine-1-acetic acid monohydrochloride.

Category: Antihypertensive and Vasodilator

Clinical Pharmacology:

Pharmacodynamics

ACEPTOR® (Benazepril) after being hydrolyzed in the liver to benazeprilat, the drug inhibits the conversion of angiotensin-I to angiotensin-II by inhibiting angiotensin-converting enzyme (ACE). Angiotensin-II acts both as a vasoconstrictor and stimulates production of aldosterone in the adrenal cortex. By blocking angiotensin-II formation, ACE inhibitors generally reduce blood pressure in hypertensive patients and vascular resistance in patients with congestive heart failure.

When administered to dogs with heart failure at low dosages (0.1 mg/kg q12h), benazepril improved clinical signs, but did not significantly affect blood pressure.

In cats with chronic renal failure, benazepril has been shown to reduce systemic arterial pressure and glomerular capillary pressure while increasing renal plasma flow and glomerular filtration rates. It may also help improve appetite. Benazepril does not contain a sulfhydryl group, so it did not cause any immune-mediated reactions like other ACE inhibitors.

Pharmacokinetics:

In Dogs, ACEPTOR® (Benazepril) is rapidly absorbed and converted into the active metabolite benazeprilat with peak levels of benazeprilat occurring approximately 75 minutes after dosing. The elimination half-life of benazeprilat is approximately 3.5 hours in healthy dogs.
In Cats, inhibition of ACE is long-lasting (half-life of 16 – 23 hours), despite relatively quick elimination of free benazeprilat, due to high affinity of benazeprilat to ACE.

Benazepril and benazeprilat are primarily eliminated via the kidneys and mild to moderate renal dysfunction apparently does not significantly alter elimination as biliary clearance may compensate somewhat for reductions in renal clearances. Hepatic dysfunction or age does not appreciably alter benazeprilat levels.

INDICATIONS:

ACEPTOR® (Benazepril) may be useful as a vasodilator in the treatment of heart failure and as an antihypertensive agent, particularly in dogs. Reasonable evidence exists that ACE-inhibitors increase survival (when compared to placebo) in dogs with dilated cardiomyopathy and mitral valve disease. Benazepril may be of benefit in treating the clinical signs associated with valvular heart disease and left to right shunts. ACE inhibitors may also be of benefit in the adjunctive treatment of chronic renal failure and for protein losing nephropathies.

In cats, benazepril can be used for treating hypertension, adjunctive treatment of hypertrophic cardiomyopathy, and reducing protein loss associated with chronic renal failure.

Dosage and Administration:

Dogs and Cats: 0.25 – 0.5 mg/kg PO once or twice daily

Contraindications:

The use of drug is contraindicated in patients who have demonstrated hypersensitivity to the ACE inhibitors.

ACE inhibitors should be used with caution in patients with hyponatremia or sodium depletion, coronary or cerebrovascular insufficiency, preexisting hematologic abnormalities or a collagen vascular disease (e.g., SLE). Patients with severe CHF should be monitored very closely upon initiation of therapy.

Warnings: Keep out of reach of children. Not for human use.

Adverse Effects:
Benazepril's adverse effect profile in dogs is not well described. Potentially, hypotension, renal dysfunction and hyperkalemia could occur.
In healthy cats given mild overdoses (2 mg/kg PO once daily for 52 weeks), only increased food consumption and weight were noted.

Reproductive / Nursing safety:
Benazepril apparently crosses the placenta. High doses of ACE inhibitors in rodents have caused decreased fetal weights and increases in fetal and maternal death rates; no teratogenic effects have been reported to date, but use during pregnancy should occur only when the potential benefits of therapy outweigh the risks to the offspring.

Interactions:
The following drug interactions have been reported in animals receiving benazepril:
Aspirin: Aspirin may negate the decrease in systemic vascular resistance induced by ACE inhibitors.
Antidiabetic agents (insulin, oral agents): Possible increased risk for hypoglycemia; enhanced monitoring recommended
Diuretics (e.g., furosemide, hydrochlorothiazide): Increased hypotensive effects and recommended to reduce furosemide doses (by 25 – 50%) when adding benazepril to therapy for heart failure
Diuretics, Potassium-sparing (e.g., spironolactone, triamterene): Increased hyperkalemic effects, enhanced monitoring of serum potassium
Lithium: Increased serum lithium levels possible; increased monitoring required
Potassium supplements: Increased risk for hyperkalemia

Presentation: Blister of 10 tablets

Storage: Store in a cool and dry place below 30^0C.

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