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# Animalcare Limited

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## **BENAZECARE® FLAVOUR 20MG TABLETS**

**Presentation** Beef flavoured, beige, divisible oval tablets. Each tablet contains 20mg benazepril hydrochloride.

**Uses** After oral administration, benazepril is rapidly absorbed from the gastrointestinal tract and hydrolysed into benazeprilat, a highly specific and potent inhibitor of angiotensin converting enzyme (ACE). Benazeprilat produces significant inhibition of plasma ACE activity for more than 24 hours after a single dose in dogs. Inhibition of ACE leads to a reduced conversion of inactive angiotensin I into angiotensin II and therefore reduction in the effects mediated by angiotensin II, including vasoconstriction of both arteries and veins, retention of sodium and water by the kidney and remodelling effects (including pathological cardiac hypertrophy).

In dogs with heart failure, benazeprilat lowers the blood pressure and volume loading effect on the heart. Onset of clinical efficacy can be expected approximately 1 week after initiation of treatment with benazepril hydrochloride. Benazeprilat is excreted equally by both biliary and urinary routes in dogs and therefore no adjustment of the dose of the product is necessary in the treatment of cases with renal insufficiency.

**Dosage and administration** The recommended dose is 0.25 mg benazepril hydrochloride/kg body weight, to be given orally once daily. The dose may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon. The dosing regime is as follows:

Weight (kg)	BENAZECARE 20mg	
	Standard dose	Double dose
21-40	0.5 tablet/day	1 tablet/day
41-80	1 tablet/day	2 tablets/day

Benazecare can be given with or without food. The duration of treatment is unlimited.

Benazepril may be given with digoxin, diuretics and anti-arrhythmic drugs as necessary.

**Contra-indications, warnings, etc** For animal treatment only.

For oral use only.

Do not use in any dog that has evidence of cardiac output failure, for example, due to aortic stenosis.

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

On rare occasions, transient signs of hypotension, such as lethargy and ataxia may occur, especially at the start of treatment.

As is routine in cases of chronic renal insufficiency, it is recommended to monitor plasma creatinine and urea during therapy.

Do not use in pregnant or nursing bitches, or in bitches intended for breeding. Studies in laboratory animals (rats) have shown embryotoxic effects of benazepril at non-maternotoxic doses (urinary tract abnormalities in the foetus). The safety of the product has not been assessed during pregnancy and lactation in dogs.

Laboratory studies in rats and observations in humans have produced evidence of teratogenic effects.

In dogs with heart failure, benazepril has been given in combination with digoxin, diuretics and anti-arrhythmic drugs without demonstrable adverse interactions.

In healthy dogs overdose up to 200-fold was asymptomatic. Transient reversible hypotension may occur in cases of accidental overdose. Symptomatic treatment should consist of intravenous infusion of warm isotonic saline.

In man, the combination of ACE inhibitors and NSAIDs can lead to reduced anti-hypertensive efficacy or impaired renal function. The combination of benazepril and other anti-hypertensive agents (e.g. calcium channel blockers, b-blockers or diuretics), anaesthetics or sedatives may lead to additive hypotensive effects. Therefore concurrent use of NSAIDs or other medications with a hypotensive effect should be considered with care. Renal function and signs of hypotension (lethargy, weakness etc) should be monitored closely and treated as necessary.

Interactions with potassium preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. It is recommended to monitor plasma potassium levels when using benazepril in combination with a potassium sparing diuretic as life threatening reactions are a possibility.

**User warnings:** Pregnant women should take special care to avoid accidental exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Wash hands after use.

In case of accidental ingestion by children, seek medical advice immediately and show this label to the doctor.

**Pharmaceutical precautions** Keep out of the reach and sight of children.

Do not store above 25°C

Store in a dry place

Return any halved tablet to the blister pack and use within 2 days.

Keep the blister pack in the outer carton.

Do not use after the expiry date stated on the carton.

*Disposal:* Any unused products or waste materials should be disposed of in accordance with national requirements.

**Packaging Quantities** Aluminium blister packs containing 14 tablets packed in a cardboard box with a package leaflet. Benazecare Flavour 20mg tablets are supplied in packs of 14, 28, 56 or 140 tablets. Not all pack sizes may be marketed.

**Further information** No evidence of renal toxicity to benazepril has been observed in dogs during clinical trials. The biliary excretion of benazepril means there is little risk of bioaccumulation in dogs with impaired renal function.

**UK**

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**IE**

VPA 10778/3/2

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