

Benazecare Flavour 5mg Tablets for Dogs and Cats

Introduction



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Presentation

Beef flavoured, beige, divisible oval tablets. Each tablet contains 5 mg benazepril hydrochloride.

Uses

Benazecare is indicated for the treatment of congestive heart failure in dogs and the treatment of chronic renal insufficiency in cats.

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 both dogs and cats. 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 and degenerative renal changes).

In dogs with heart failure, benazeprilat lowers the blood pressure and volume loading effect on the heart.

In cats with renal insufficiency, benazeprilat reduces the protein loss in urine and normalises the elevated glomerular capillary pressure and reduces systemic blood pressure. Reduction in glomerular hypertension retards the progression of kidney disease by inhibition of further damage to the kidneys. Benazepril has been shown to increase the appetite, quality of life and the survival time of cats particularly in advanced disease.

Benazeprilat is excreted equally by both biliary and urinary routes in dogs and primarily via the biliary route in cats and therefore no adjustment of the dose of Benazecare is necessary in the treatment of cases with renal insufficiency. Onset of clinical efficacy can be expected approximately 1 week after initiation of treatment with benazepril hydrochloride.

Dosage and administration

In both dogs and cats, Benazecare should be given orally once daily with or without food. The duration of treatment is unlimited.

Congestive Heart Failure in Dogs

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:

BENZAECARE 5mg		
Weight of dog (kg)	Standard dose	Double dose
5-10	0.5 tablet/day	1 tablet/day
11-20	1 tablet/day	2 tablets/day

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

Chronic renal insufficiency in cats

The recommended oral dose is 0.5 mg benazepril hydrochloride/kg body weight according to the following table:

BENZAECARE 5mg	
Weight of cat (kg)	
2.5 - 5	0.5 tablet/day
>5 - 10	1 tablet/day

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 in dogs, transient signs of hypotension such as lethargy and ataxia may occur especially at the start of treatment.

In cats with chronic renal insufficiency, benazepril may increase plasma creatinine concentrations at the start of therapy. This effect is related to the therapeutic effect of the product in reducing blood pressure, and therefore is not necessarily a reason to stop therapy in the absence of other signs. As is routine in cases of chronic renal insufficiency, it is recommended to monitor plasma creatinine during therapy.

Benazepril 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. As is routine in cases of chronic renal insufficiency, it is recommended to monitor erythrocyte counts during therapy. Benazepril may increase food consumption and body weight in cats. Emesis, anorexia, dehydration and lethargy have been reported on rare occasions in this species.

As is routine in cases of chronic renal insufficiency, it is recommended to monitor plasma creatinine and urea during therapy. The efficacy and safety of benazepril has not been established in cats below 2.5 kg body weight.

Do not use in pregnant or nursing bitches or queens, or in bitches or queens 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 breeding or in pregnant or lactating dogs and cats. Benazepril reduces ovary/oviduct weights in cats when administered daily at 10 mg/kg for 52 weeks.

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. In healthy cats overdose up to 10-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, β -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.

Legal category

POM-V

Packaging Quantities

Aluminium blister packs containing 14 tablets packed in a cardboard box with a package leaflet. Benazecare Flavour 5 mg 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 or cats during clinical trials. The biliary excretion of benazepril means there is little risk of bioaccumulation in dogs with impaired renal function.

Marketing authorisation number

Vm 10347/4021

GTIN (Global Trade Item No)

28 Tablets:

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