PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benazecare Flavour 5 mg Tablets for Dogs and Cats.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride 5mg

3. PHARMACEUTICAL FORM

Tablet
Beef flavoured, beige, divisible oval tablets.

4. PACKAGE SIZE

14 tablets
28 tablets
56 tablets
140 tablets

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

For the treatment of congestive heart failure in dogs.
For reduction of proteinuria associated with chronic kidney disease in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in a dry place.
Divided tablets should be stored in the blister pack. Any divided tablet portion remaining after 48 hours should be discarded. Keep the blister pack in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4038
POM-V

VPA 10778/003/001
POM

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benazecare Flavour 5 mg Tablets for Dogs and Cats.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Benazecare Flavour 5 mg Tablets for Dogs and Cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer for the batch release:
Lelypharma B.V.
Zuiveringweg 42,
8243 PZ
Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benazecare Flavour 5 mg Tablets for Dogs and Cats.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATIONS

Benazecare Flavour 5mg tablets belong to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It is prescribed by the veterinary surgeon for the treatment of congestive heart failure in dogs and for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatraemia (low blood sodium levels) or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in pregnant or lactating dogs or cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.
In dogs and cats with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

Benazepril hydrochloride may increase food consumption and body weight in cats. Vomiting, poor appetite, dehydration, lethargy and diarrhoea have been reported on rare occasions in cats.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Benazecare Flavour 5mg tablets should be given orally once daily, with or without food. The duration of treatment is unlimited.

In dogs, Benazecare Flavour 5mg tablets should be administered orally at a minimum dose of 0.25 mg (range 0.25-0.5) benazepril hydrochloride/kg body weight once daily, according to the following table:

	BENAZECARE FLAVOUR 5mg	
Weight of dog (kg)	Standard Dose	Double Dose
5 – 10	0.5 tablet	1 tablet
>10 – 20	1 tablet	2 tablets

In dogs with congestive heart failure, the dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight if judged necessary and advised by the veterinary surgeon. Always follow the dosing instructions given by the veterinary surgeon.

In cats, Benazecare Flavour 5mg tablets should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

Weight of cat (kg)	BENAZACARE FLAVOUR 5mg
2.5 – 5	0.5 tablet
>5 - 10	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Store in a dry place.
Divided tablets should be stored in the blister pack. Any divided tablet portion remaining after 48 hours should be discarded. Keep the blister pack in the outer carton.
Do not use after the expiry date stated on the carton.

12. SPECIAL WARNINGS

Special warnings for dogs and cats
The efficacy and safety of benazepril hydrochloride has not been established in dogs and cats below 2.5 kg body weight.

Special precautions for use in animals
In cases of chronic kidney disease, your veterinarian will check the hydration status of your pet before starting therapy, and may recommend that regular blood tests are carried out during therapy in order to monitor plasma creatinine concentrations and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.
Pregnant women should take special care to avoid accidental oral exposure because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

Use during pregnancy, lactation
Do not use during pregnancy or lactation. The safety of benazepril hydrochloride has not been established in breeding, pregnant or lactating dogs or cats.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, benazepril hydrochloride has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic products without evidence of associated adverse reactions.

In humans, the combination of ACE inhibitors and NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. The combination of benazepril hydrochloride 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.
Your veterinary surgeon may recommend to closely monitor kidney function and for signs of hypotension (lethargy, weakness etc) and treat these if necessary.

Interactions with potassium-preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. Your veterinary surgeon may recommend to monitor plasma potassium concentrations when using benazepril hydrochloride in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose
Transient reversible hypotension (low blood pressure) may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

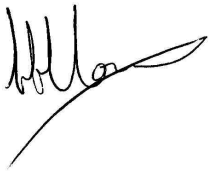
15. OTHER INFORMATION

Pharmacodynamic properties
Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat.
Benazeprilat is a highly potent and selective inhibitor of the angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I to active angiotensin II and thereby also reducing synthesis of aldosterone. Therefore, it blocks effects mediated by angiotensin II and aldosterone, 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).
Benazepril hydrochloride causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

Benazepril hydrochloride reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, benazepril hydrochloride normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys. In a clinical trial in cats with chronic kidney disease, benazepril hydrochloride significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. Benazepril hydrochloride also increased the appetite of the cats, particularly in more advanced cases.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and 85% via the biliary and 15% via the urinary route in cats, and therefore no adjustment of the dose of benazepril hydrochloride is necessary in the treatment of cases with renal insufficiency.



Approved 12 October 2022