[Version 9, 03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Banacep Vet 5 mg film-coated tablets for dogs and cats [BE, DE, EL, ES, IE, IT, NL, PL, PT, RO, UK]

Banacep Vet 5 film-coated tablets for dogs and cats [FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Benazepril ..... 4.6 mg
(equivalent to Benazepril Hydrochloride 5 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Iron oxide yellow (E 172)	0.117 mg
Iron oxide red (E 172)	0.014 mg
Iron oxide black (E 172)	0.004 mg
Titanium dioxide (E 171)	1.929 mg
Cellulose microcrystalline	
Lactose monohydrate	
Povidone	
Maize starch	
Silica colloidal anhydrous	
Magnesium stearate	
Hypromellose	
Macrogol 8000	

Beige oblong biconvex film-coated divisible tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

Dogs:
Treatment of congestive heart failure.

Cats:
Reduction of proteinuria associated with chronic kidney disease.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use during pregnancy or lactation (see section 3.7).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

No evidence of renal toxicity of the veterinary medicinal product has been observed in dogs or cats during clinical trials however, as is routine in cases of chronic kidney disease, it is recommended to monitor plasma creatinine, urea and erythrocyte counts during therapy.

The efficacy and the safety of the veterinary medicinal product has not been established in dogs and cats below 2.5 kg body weight.

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 angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):	Vomiting Incoordination Fatigue Elevated creatinine*

*In dogs with chronic kidney disease, at the start of therapy. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents and is therefore not necessarily a reason to stop therapy in the absence of other signs.

In double-blind clinical trials in dogs with congestive heart failure, the veterinary medicinal product was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Emesis Anorexia, Dehydration, Lethargy
Undetermined frequency (cannot be estimated from the available data):	Elevated creatinine* Increased appetite, Weight gain

*In cats with chronic kidney disease, at the start of therapy. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents and is therefore not necessarily a reason to stop therapy in the absence of other signs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy or lactation.

The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating dogs and cats.

Benazepril reduced ovary / oviduct weights in cats when administered daily at 10 mg/kg body weight for 52 weeks. Embryotoxic effects o (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

3.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, the veterinary medicinal product has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products without demonstrable adverse interactions.

In humans, the combination of ACE inhibitors and Non-Steroidal Anti-Inflamatory Drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired renal function. The combination of the veterinary medicinal product 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 the veterinary medicinal product in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

3.9 Administration route and dosage

Oral use.

The veterinary medicinal product should be given orally once daily, with or without food. The duration of treatment is unlimited.

Dogs:

The veterinary medicinal product 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:

Weight of dog (kg)	Banacep Vet 5 mg Film-Coated Tablets	
	Standard dose	Double dose
> 5 - 10	0.5 tablet	1 tablet
>10 - 20	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

Cats:
The veterinary medicinal product should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kgbody weight once daily: according to the following table:

Weight of cat (kg)	Banacep Vet 5 mg Film-Coated Tablets
2.5 – 5	0.5 tablet
> 5 - 10	1 tablet

3.10 Symptom of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats or dogs.

Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code: QC09AA07

4.2 Pharmacodynamics

Benazepril hydrochloride is a prodrug hydrolysed in vivo to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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).

The veterinary medicinal product 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.

The veterinary medicinal product reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In cats with experimental renal insufficiency, the veterinary medicinal product 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. Placebo controlled clinical field studies in cats with chronic kidney disease (CKD) have demonstrated that the veterinary medicinal product significantly reduced levels of urine protein and urine protein to creatinine ratio (UPC); this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane.

No effect of the veterinary medicinal product on survival in cats with CKD has been shown, but the veterinary medicinal product increased the appetite of the cats, particularly in more advanced cases.

4.3 Pharmacokinetics

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs and within 2 hours in cats) and decline quickly as the active substance is partially metabolised by liver enzymes to benazeprilat. The systemic bioavailability is incomplete (~13% in dogs) due to incomplete absorption (38% in dogs, <30% in cats) and first pass metabolism.

In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.
In cats, peak benazeprilat concentrations (C_{max} of 77.0 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 2 hours.
Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$ = 1.7 hours in dogs and $t_{1/2}$= 2.4 hours in cats) represents elimination of free drug, while the terminal phase ($t_{1/2}$ = 19 hours in dogs and $t_{1/2}$= 29 hours in cats) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of the veterinary medicinal product leads to slight bioaccumulation of benazeprilat (R=1.47 in dogs and R=1.36 in cats with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs and 85% via the biliary and 15% via the urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of the veterinary medicinal product dose is required in either species in cases of renal insufficiency.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf-life of tablet halves: 24 hours

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.
Return any halved tablet to the open blister space and use within 1 day. The blister pack should be inserted back into the cardboard box.

5.4 Nature and composition of immediate packaging

Blister made of clear film of PVC/PE/PVDC and aluminium film containing 14 tablets.

Box with:
- 1 blister (14 tablets)
- 10 blisters (140 tablets)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A. [BE, FR, DE, EL, ES, IE, IT, PL, NL, RO, UK]

CALIER PORTUGAL S.A. [PT]

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}.>

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 1 blister (14 tablets) or 10 blisters (140 tables)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Banacep Vet 5 mg film-coated tablets [BE, DE, EL, ES, IE, IT, NL, PL, PT, RO, UK]

Banacep Vet 5 film-coated tablets [FR]

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Benazepril ..... 4.6 mg
(equivalent to Benazepril Hydrochloride 5 mg)

3. PACKAGE SIZE

14 tablets
140 tablets

4. TARGET SPECIES

Dogs, cats.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in a dry place.
Return any halved tablet to the open blister space and use within 1 day. The blister pack should be inserted back into the cardboard box.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A. [BE, FR, DE, EL, ES, IE, IT, PL, NL, RO, UK(NI)]

CALIER PORTUGAL S.A. [PT]

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister with 14 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Banacep Vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Benazepril 4.6 mg/tablet
(equivalent to Benazepril Hydrochloride 5 mg/tablet)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Banacep Vet 5 mg film-coated tablets for dogs and cats [BE, DE, EL, ES, IE, IT, NL, PL, PT, RO, UK]

Banacep Vet 5 film-coated tablets for dogs and cats [FR]

2. Composition

Each tablet contains:

Active substance:
Benazepril .....4.6 mg
(equivalent to Benazepril Hydrochloride 5 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Iron oxide yellow (E-172)	0.117 mg
Iron oxide red (E-172)	0.014 mg
Iron oxide black (E-172)	0.004 mg
Titanium dioxide (E-171)	1.929 mg

Beige oblong biconvex film-coated divisible tablets.

3. Target species

Dogs, cats.

4. Indications for use

Dogs: Treatment of congestive heart failure.

Cats: Reduction of proteinuria associated with chronic kidney disease.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
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 during pregnant or lactation (see section 6).

6. Special warnings

Special precautions for safe use in the target species:

No evidence of renal toxicity of the veterinary medicinal product has been observed in dogs or cats during clinical trials however, as is routine in cases of chronic kidney disease, it is recommended to monitor plasma creatinine, urea and erythrocyte counts during therapy.

The efficacy and safety of the veterinary medicinal product has not been established in dogs and cats below 2.5 kg body weight.

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 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 angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

Pregnancy and lactation:

Do not use during pregnancy or lactation.

The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating dogs or cats.

Benazepril reduced ovary/oviduct weights in cats when administered daily at 10 mg/kg body weight for 52 weeks. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

Interaction with other medicinal products and other forms of interaction:

Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.

In dogs with congestive heart failure, the veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose:

The veterinary medicinal product reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and in normal dogs when dosed at 150 mg/kg body weight once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in cats or dogs.

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

7. Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):	Vomiting Incoordination Fatigue Elevated creatinine*

*In dogs with chronic kidney disease, at the start of therapy. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents and is therefore not necessarily a reason to stop therapy in the absence of other signs.

In double-blind clinical trials in dogs with congestive heart failure, the product was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Emesis Anorexia, Dehydration, Lethargy
Undetermined frequency (cannot be estimated from the available data):	Elevated creatinine* Increased appetite, Weight gain

*In cats with chronic kidney disease at the start of therapy. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents and is therefore not necessarily a reason to stop therapy in the absence of other signs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}

8. Dosage for each species, routes and method of administration

The veterinary medicinal product should be given orally once daily, with or without food. The duration of treatment is unlimited.

In dogs, the veterinary medicinal product 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:

Weight of dog (kg)	Banacep Vet 5 mg Film-Coated Tablets	
	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, the veterinary medicinal product 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)	Banacep Vet 5 mg Film-Coated Tablets
2.5 – 5	0.5 tablet
> 5 - 10	1 tablet

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children

Do not store above 25°C.
Store in a dry place.
Return any halved tablet to the open blister space and use within 1 day. The blister pack should be inserted back into the cardboard box.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
1 blister (14 tablets)
10 blisters (140 tablets)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

LABORATORIOS CALIER, S.A. [BE, FR, DE, EL, ES, IE, IT, PL, NL, RO, UK]
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona
Spain

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra
Portugal

<Manufacturer responsible for batch release:

LABORATORIOS CALIER S.A.
C. Barcelonès, 26
Polígono Industral del Ramassà
08520 Les Franqueses del Vallès
Barcelona
Spain>

<Local representatives <and contact details to report suspected adverse reactions>:>

[To be completed nationally]

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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 remodeling effects (including pathological cardiac hypertrophy and degenerative renal changes).
The veterinary medicinal product 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.
The veterinary medicinal product reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.
In cats with experimental renal insufficiency, the veterinary medicinal product 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.
Placebo controlled clinical field studies in cats with chronic kidney disease (CKD) have demonstrated that the veterinary medicinal product significantly reduced levels of urine protein and urine protein to creatinine ratio (UPC); this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. No effect of the veterinary medicinal product on survival in cats with CKD has been shown, but the veterinary medicinal product increased the appetite of the cats, particularly in more advanced cases.
Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs and 85% via the biliary and 15% via the urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of the veterinary medicinal product dose is required in either species in cases of renal insufficiency.