ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benamax Flavour 5 mg tablets for cats and dogs
(in Czech Republic, Hungary, Latvia and Lithuania)

Benefortin Flavour 5 mg tablets for cats and dogs
(in Austria, Belgium, Germany, Ireland, Luxembourg, Netherlands, Portugal, Spain and United Kingdom)

Benefortin 5 tablet for cats and dogs
(*in France*)

Scanopril Flavour 5 mg tabletki dla kotów i psów
(in Poland)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance Benazepril hydrochloride: 5.0 mg (equivalent to Benazepril 4,60 mg)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
Brownish, oval, divisible, tablet scored on both sides. The tablets can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:
Treatment of congestive heart failure.

Cats:
Reduction of proteinuria associated with chronic kidney disease.

4.3 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 (section 4.7).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 benazepril has not been established in dogs and cats below 2.5 kg body weight.
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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.

4.6 Adverse reactions (frequency and seriousness)

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

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue. In cats and dogs with chronic kidney disease, benazepril may increase plasma creatinine concentrations 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.
Benazepril may increase food consumption and body weight in cats. Emesis, anorexia, dehydration, lethargy and diarrhoea have been reported in rare occasions in cats.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation. The safety of benazepril hydrochloride 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 (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

4.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, benazepril hydrochloride 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-Inflammatory Drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired renal 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. 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 because of the risk of hyperkalaemia.

4.9 Amounts to be administered and administration route

The veterinary medicinal product should be given orally once daily, with or without food. The duration of treatment is unlimited.
The tablets are flavoured and are taken voluntarily by most dogs and cats.
Dogs:
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:

Weight of dog (kg)	Benamax/Benefortin Flavour 5mg	
	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 dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

Cats:
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)	Benamax / Benefortin Flavour 5 mg
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Benazepril 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.

4.11 Withdrawal period(s)

Not applicable.

5. <PHARMACOLOGICAL><IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group: ACE Inhibitors, plain.
ATC vet code: QC09AA07.

5.1 Pharmacodynamic properties>

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).

Benazeprilat 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 reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.
In cats with experimental renal insufficiency, benazepril 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 benazepril 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 benazepril hydrochloride on survival in cats with CKD has been shown, but benazepril hydrochloride increased the appetite of the cats, particularly in more advanced cases.

5.2 Pharmacokinetic particulars

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 benazepril 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 urinary route in cats. The clearance of benazeprilat is not affected in dogs or cats with impaired renal function and therefore no adjustment of dose of the veterinary medicinal product is required in either species in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, microcrystalline
Wheat starch
Sodium starch glycolate (Type A)
Glycerol distearate
Dried yeast
Liver powder flavour
Talc

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of veterinary medicinal product as packaged for sale: 18 months.
Tablet halves should be used within 2 days.

6.4. Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the cardboard box and kept in a safe place out of the reach of children.

6.5 Nature and composition of immediate packaging

PVC/Aluminium/Polyamide blister -forming laminate with aluminium lidding foil with 14 tablets/blister.
Cardboard box with 1 blister strip of 14 tablets (14 tablets)
Cardboard box with 2 blister strips of 14 tablets (28 tablets)
Cardboard box with 4 blister strips of 14 tablets (56 tablets)
Cardboard box with 10 blister strips of 14 tablets (140 tablets)

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
2143 Kistarcsa, Batthyány u. 6.
Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benamax/Benefortin/Scanopril Flavour 5 mg tablets for cats and dogs
Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance Benazepril hydrochloride 5.0 mg (equivalent to Benazepril 4.60 mg)

3. PHARMACEUTICAL FORM

Tablet.
Brownish, oval, divisible tablet scored on both sides. The tablets can be divided into equal halves.

4. PACKAGE SIZE

Box containing 1 blister strip of 14 tablets (14 tablets)
Box containing 2 blister strips of 14 tablets (28 tablets)
Box containing 4 blister strips of 14 tablets (56 tablets)
Box containing 10 blister strips of 14 tablets (140 tablets)

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

For 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(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Tablet halves should be used within 2 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the cardboard box.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.,
2143 Kistarcsa, Batthyány u. 6., Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benamax 5 mg tablets
Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Pouze pro zvířata.
Kizárólag állatgyógyászati alkalmazásra.
Lietošanai dzīvniekiem.
Tik veterinariniam naudojimui.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benefortin 5 mg tablets
(FR: Benefortin 5 compr.)
Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Für Tiere.
For animal treatment only.
Uitsluitend voor diergeneeskundig gebruik.
Uso veterinario.
Usage vétérinaire.
Uso veterinário.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scanopril Flavour 5 mg tabletki
Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Wyłącznie dla zwierząt.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Benamax/Benefortin Flavour 2.5 mg tablets for cats and dogs
Benamax/Benefortin Flavour 5 mg tablets for cats and dogs
Benamax/Benefortin Flavour 20 mg tablets for dogs

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

Lavet Pharmaceuticals Ltd.,
2143 Kistarcsa, Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benamax Flavour 2.5 mg tablets for cats and dogs
Benamax Flavour 5 mg tablets for cats and dogs
Benamax Flavour 20 mg tablets for dogs
(in Czech Republic, Hungary, Latvia and Lithuania)

Benefortin Flavour 2.5 mg tablets for cats and dogs
Benefortin Flavour 5 mg tablets for cats and dogs
Benefortin Flavour 20 mg tablets for dogs
(in Austria, Belgium, Germany, Ireland,, Luxembourg, Netherlands,, Portugal, Spain and United Kingdom)

Benefortin 2.5 tablet for cats and dogs
Benefortin 5 tablet for cats and dogs
Benefortin 20 tablet for dogs
(in France)

Scanopril Flavour 2,5 mg tabletki dla kotów i psów
(in Poland)

Benazepril hydrochloride

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

Active substance	Benazepril hydrochloride: 2.5 mg	(equivalent to Benazepril 2.30 mg)
	Benazepril hydrochloride: 5 mg	(equivalent to Benazepril 4.60 mg)
	Benazepril hydrochloride: 20 mg	(equivalent to Benazepril 18.4 mg)

Brownish, oval, divisible, tablet scored on both sides. The tablets can be divided into equal halves.

4. INDICATION(S)

Benazepril hydrochloride belongs 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 cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension (low blood pressure), hypovolaemia (low blood volume), 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 (section 12.).

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 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 not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs (2,5 mg, 5 mg, 20 mg) and cats (2,5 mg, 5 mg).

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

The veterinary medicinal product should be given orally once daily, with or without food. The duration of treatment is unlimited.
The tablets are flavoured and are taken voluntarily by most dogs and cats.

2.5 mg tablets
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)	Benamax / Benefortin Flavour 2.5 mg	
	Standard dose	Double dose
2.5 - 5	0.5 tablet	1 tablet
>5 – 10	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.

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)	Benamax / Benefortin Flavour 2.5 mg
2.5 – 5	1 tablet
>5 – 10	2 tablets

5 mg tablets
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)	Benamax / Benefortin Flavour 5 mg	
	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.

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)	Benamax / Benefortin Flavour 5 mg
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

20 mg tablets
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)	Benamax / Benefortin Flavour 20 mg	
	Standard dose	Double dose
20-40	0.5 tablet	1 tablet
>40-80	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

9. ADVICE ON CORRECT ADMINISTRATION

For oral use only.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the cardboard box and kept in a safe place out of the reach of children.
Tablet halves should be used within 2 days.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP (month/year). The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Pregnancy and 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.

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, benazepril 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 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 (symptoms, emergency procedures, antidotes):
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 MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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 "product name" (to be completed nationally) is necessary in the treatment of cases with renal insufficiency.

2.5 mg and 5 mg tablets
PVC/Aluminium/Polyamide blister -forming laminate with aluminium lidding foil with 14 tablets/blister.
Cardboard box with 1 blister strip of 14 tablets (14 tablets)
Cardboard box with 2 blister strips of 14 tablets (28 tablets)
Cardboard box with 4 blister strips of 14 tablets (56 tablets)
Cardboard box with 10 blister strips of 14 tablets (140 tablets)

20 mg tablets
PVC/Aluminium/Polyamide blister -forming laminate with aluminium lidding foil with 7 tablets/blister.
Cardboard box with 1 blister strip of 7 tablets (7 tablets)
Cardboard box with 2 blister strips of 7 tablets (14 tablets)
Cardboard box with 4 blister strips of 7 tablets (28 tablets)
Cardboard box with 10 blister strips of 7 tablets (70 tablets)

Not all pack sizes may be marketed.

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