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)

Vm 32823/4007

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

June 2020

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

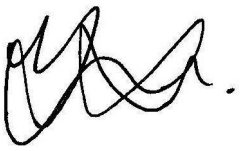
24 hours after dosing. Benazepril hydrochloride reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.
In cats with experimental renal insufficiency, benazepril hydrochloride normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. 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.



Approved: 18 June 2020