ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fortekor Flavour 5 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

5 mg benazepril hydrochloride

3. PACKAGE SIZE

14 tablets
28 tablets
56 tablets
140 tablets

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of tablet halves: 2 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Each time an unused half tablet is stored, it should be returned to the open blister space, inserted back into the cardboard box and kept in a safe place out of the sight and reach of children.

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

Elanco Europe Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/3016

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fortekor Flavour


2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fortekor Flavour 5 mg tablets for cats and dogs

2. Composition

Each tablet contains 5 mg benazepril hydrochloride.
Beige to light brown, ovaloid, divisible tablets, scored on both sides.
The tablets can be divided into equal halves.

3. Target species

Dogs and cats.

4. Indications for use

The veterinary medicinal product 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), 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. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
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, urea and blood erythrocyte counts.

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

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation and in breeding animals.
Do not use during pregnancy or lactation.

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

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Vomiting, Fatigue
Very rare *(<1 animal / 10,000 animals treated, including isolated reports):*
Elevated creatinine[1], Incoordination

[1]In dogs with chronic kidney disease, the product 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.

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Diarrhoea, Emesis, Anorexia, Dehydration, Lethargy
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated creatinine[1], Increased appetite, Weight gain

[1]In cats with chronic kidney disease, the product 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.

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.

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

Oral use.

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

This product is flavoured and is taken voluntarily by most dogs and cats.

In dogs, this veterinary medicinal product should be administered 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)	**5 mg tablet strength**	
	Standard dose	Double dose
5 - 10	0.5 tablet	1 tablet
>10 - 20	1 tablet	2 tablets

In dogs, 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, this veterinary medicinal product should be administered 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)	**5 mg tablet strength**
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

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

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 or blister after Exp. The expiry date refers to the last day of that month.

Shelf life of tablet halves: 2 days.

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 national collection systems applicable to the veterinary medicinal product concerned. 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

Vm 00879/3016

14 tablets per aluminium/aluminium blister. Cardboard box with:
1 blister (14 tablets)
2 blisters (28 tablets)
4 blisters (56 tablets)
10 blisters (140 tablets)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Elanco France S.A.S.
Usine de Huningue 26,
Rue de la Chapelle
F-68332 Huningue Cedex
France

Local representatives and contact details to report suspected adverse reactions:

17. Other information

Pharmacodynamics
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).

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 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. In a clinical trial in cats with chronic kidney disease, the product significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. The veterinary medicinal product 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 the product is necessary in the treatment of cases with renal insufficiency.

Approved 31 August 2023