Revised: August 2016
AN: 00397/2016

PACKAGE LEAFLET FOR:
FORTEKOR 5 mg
Film-coated tablets for cats and dogs

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

Marketing authorisation holder:
Elanco Europe Ltd
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

Manufacturer for the batch release:
Elanco France S.A.S
26 Rue de la Chapelle
F-68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR 5 mg
Film-coated tablets for cats and dogs

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

Each film-coated tablet contains 5 mg benazepril hydrochloride
Light yellow, ovaloid, slightly biconvex tablets with score on both sides, marked "CG" on one side and "LV" on the reverse.

4. INDICATIONS

FORTEKOR 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 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), hypovolaemia (low blood volume) 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.

FORTEKOR 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 AND METHOD OF ADMINISTRATION

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

In dogs FORTEKOR 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	FORTEKOR□□ 5 mg	
	Standard	Double
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 FORTEKOR 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	FORTEKOR□□5 mg
2.5 – 5	0.5 tablet
>5 – 10	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

For oral use only.
For animal treatment only.
Wash hands after use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Store in a dry place.
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 reach of children.

No special temperature storage conditions required.

12. SPECIAL WARNINGS

Special warnings for dogs and cats
The efficacy and safety of FORTEKOR 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 FORTEKOR 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, FORTEKOR 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 FORTEKOR and other anti-hypertensive agents (e.g. calcium channel blockers, □-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 FORTEKOR 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 MATERIALS, IF ANY

Dispose of used packaging in the household refuse.
Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<To be completed in accordance with national requirements>

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).
FORTEKOR 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.

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

In cats with experimental renal insufficiency, FORTEKOR 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, FORTEKOR significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. FORTEKOR 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 FORTEKOR is necessary in the treatment of cases with renal insufficiency.

Package quantities:
PVC/PE/PVDC blister containing 14 film-coated tablets. Cardboard box with

- 1 blister (14 tablets)
- 10 blisters (140 tablets)

Not all pack sizes may be marketed.


15 August 2016