

FORTEKOR® 2.5, 5 and 20


NOVARTIS

Presentation

Fortekor 2.5:

Palatable beige, ovaloid tablets which are scored on both sides:

2.5 mg benazepril hydrochloride (Fortekor® 2.5).

Fortekor 5 and 20:

Ovaloid, biconvex film-coated tablets which are scored on both sides.

Light yellow tablets:

5 mg benazepril hydrochloride (Fortekor® 5).

Marked "CG" on one side and "LV" on the reverse.

Reddish orange tablets:

20 mg benazepril hydrochloride (Fortekor® 20).

Marked "CG" on one side and "HP" on the reverse.

Use

Fortekor is indicated for the treatment of heart failure in dogs and chronic renal insufficiency in cats. The active ingredient is benazepril. After oral administration, benazepril is rapidly absorbed from the gastrointestinal tract and hydrolysed into benazeprilat, a highly specific and potent inhibitor of angiotensin converting enzyme (ACE). Fortekor produces significant inhibition of plasma ACE activity for more than 24 hours after a single dose in cats and dogs. Inhibition of ACE leads to reduced conversion of inactive angiotensin I into angiotensin II and therefore reduction in the effects mediated by angiotensin II, including vasoconstriction of both arteries and veins and retention of sodium and water by the kidney. In dogs with heart failure, Fortekor lowers the blood pressure and volume loading on the heart.

Fortekor leads to a significant extension of the life span of dogs with heart failure and also improves clinical signs, notably reduction in coughing and improvement of the quality of life. In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and primarily via the biliary route in cats and therefore no adjustment of the dose of Fortekor is necessary in the treatment of cases with renal insufficiency. In cats with chronic renal insufficiency, Fortekor reduces the protein loss in urine and lowers the systemic and intraglomerular blood pressure. Fortekor increases the appetite, quality of life and the survival time of the cats, particularly in advanced disease.

Dosage and Administration

Heart failure in dogs

The recommended dose is 0.25-0.5 mg benazepril hydrochloride/kg body weight, to be given orally once daily according to the following regime:

Fortekor 5		
Weight of dog (kg)	Standard dose	Double dose
5-10	0.5 tablet	1 tablet
11-20	1 tablet	2 tablets
21-40	-	-
41-80	-	-

Fortekor 20		
Weight of dog (kg)	Standard dose	Double dose
5-10	-	-
11-20	-	-
21-40	0.5 tablet	1 tablet
41-80	1 tablet	2 tablets

Fortekor can be given with or without food. The duration of treatment is unlimited. The dose may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon. When the 10 mg dose is required, veterinary surgeons should consider administering two 5 mg tablets to limit the use of half tablets.

Fortekor may be given in combination with digoxin, diuretics and anti-arrhythmic drugs as necessary.

Chronic renal insufficiency in cats

The recommended dose is 0.5-1.0 mg benazepril hydrochloride/kg body weight, to be given orally once daily according to the following regime:

Weight of cat (kg)	Fortekor 2.5	Fortekor 5
2.5-5	1 tablet	0.5 tablet
> 5-10	2 tablets	1 tablet

Fortekor can be given with or without food. The duration of the treatment will be unlimited.

Contra-Indications, Warnings etc.

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

In man, the combination of ACE inhibitors and NSAIDs can lead to reduced antihypertensive efficacy or impaired renal function. Therefore concurrent use of NSAIDs should be considered with care.

Dogs

Transient signs of hypotension such as tiredness or dizziness may appear in rare cases.

Interactions with potassium preserving drugs, like spironolactone, triamteren or amilorid cannot be ruled out. It is recommended to monitor plasma potassium levels when using benazepril in combination with a potassium sparing diuretic. As with other ACE inhibitors, the use of hypotensive medicinal products or anaesthetics with a hypotensive effect may add to the anti-hypertensive effect of benazepril. Fortekor is not recommended for breeding dogs, pregnant or lactating bitches. As is routine in cases of renal insufficiency, it is recommended to monitor plasma urea and creatinine concentrations. Do not use in any dog that has evidence of cardiac output failure due to aortic stenosis.

Cats

Fortekor may increase plasma creatinine concentrations at the start of the therapy. This effect is related to the therapeutic effect of the product in reducing blood pressure and therefore is not necessarily a reason to stop therapy in the absence of other signs. As is routine in cases of renal insufficiency, it is recommended to monitor plasma urea and creatinine concentrations and erythrocyte counts.

Fortekor reduced erythrocyte counts in normal cats at high doses, but this effect was not observed at the recommended dose during clinical trials in cats with chronic renal insufficiency. Fortekor may increase food consumption and body weight in cats. The combination of Fortekor and other anti-hypertensive agents (e.g. calcium channel blockers, β -blockers or diuretics), anaesthetics or sedatives may lead to additive hypotensive effects.

Fortekor is not recommended for breeding cats, pregnant or lactating queens. The safety and efficacy of Fortekor has not been established in cats below 2.5 kg.

Pharmaceutical Precautions

Store in a dry place. 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 reach of children.

Legal Category: POM - Prescription Only Medicine

Package Quantities

Plastic blister packs each containing 14 tablets:

- Individual pack containing 1 blister (Fortekor 5, Fortekor 20)
- Pack containing 2 blisters (Fortekor 2.5)

Further Information

No evidence of renal toxicity to Fortekor has been observed in dogs during clinical trials. The biliary excretion of benazepril means there is little risk of bioaccumulation in dogs and cats with impaired renal function.

Disposal

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

Manufacturer of the medicinal product

Novartis Santé Animale SA, 26, rue de la chapelle 68333 Huningue/France

Marketing Authorisation Numbers in UK

Fortekor 2.5: Vm 12501/4129

Fortekor 5: Vm 12501/4029

Fortekor 20: Vm 12501/4030

Novartis Animal Health UK Limited, New Cambridge House, Litlington, Nr. Royston, Hertfordshire SG8 0SS
Tel.: 01763 850500

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