ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benakor 2.5 mg, film-coated tablets for cats
(benazepril hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

2.3 mg benazepril (equivalent to 2.5 mg benazepril hydrochloride)

Excipients:
Titanium dioxide (E-171) 0.53 mg

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

14 tablets – 28 tablets – 98 tablets - 140 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

User warnings
Pregnant women and women of child-bearing age should exercise caution when handling this product – read package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store below 25°C in a dry place in original blister.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC/PCTFE – aluminium blister containing 14 film-coated tablets.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benakor 2.5 mg, film-coated tablets for cats
Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot :{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Benakor 2.5 mg, film-coated tablets for cats

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

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
KELA N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benakor 2.5 mg, film-coated tablets for cats
Benazepril hydrochloride

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

Each tablet contains 2.3 mg benazepril (equivalent to 2.5 mg benazepril hydrochloride)
White oval divisible tablets scored on both sides.
The tablets can be divided into equal halves.

Excipients:
Titanium dioxide (E-171) 0.53 mg

4. INDICATIONS

Benakor 2.5 mg film-coated tablets belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It is prescribed by the veterinary surgeon for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
Do not use in cases of hypotension (low blood pressure), hypovolemia (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 in pregnant or lactating cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

In 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 therefore is not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

Benazepril hydrochloride 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

Cats

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

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

In cats the 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)	Benakor 2.5 mg film-coated tablets
2.5 – 5 >5 – 10	1 tablet 2 tablets

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store below 25°C in original blister. Store in a dry place.
Do not use after the expiry date which is stated on the label after EXP.
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.
Tablet halves should be used within 2 days.

12. SPECIAL WARNING(S)

Special warnings for cats
The efficacy and safety of the product has not been established in cats below 2.5 kg body weight.

Special precautions for use in animals
In cases of chronic kidney disease i tis recommended that regular blood tests are carried out during therapy to monitor plasma creatinine, urea and blood erythrocyte counts.

User Warnings
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 or lay
Do not use during pregnancy or lactation. The safety of the product has not been established in breeding, pregnant or lactating cats.

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
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 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. 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. It is recommended 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

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 material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15 OTHER INFORMATION

1 blister of 14 tablets
2 blisters of 14 tablets
7 blisters of 14 tablets
10 blisters of 14 tablets

Not all pack sizes may be marketed

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 degenerative renal changes).
The product causes long-lasting inhibition of plasma ACE activity in cats, with more than 95% inhibition at peak effect and significant activity (>90% in cats) persisting 24 hours after dosing.

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.

Benazeprilat is excreted 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.