LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAKOR 20 mg film-coated tablet for dogs
Benazepril hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril **Hydrochloride** .....**20** mg

(equivalent to Benazepril **18.42** mg)

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PACKAGE SIZE

14 tablets
140 tablets

5. TARGET SPECIES

Dogs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
User warnings: Women of child-bearing age and pregnant women should exercise caution when handling this product. Read package leaflet before use

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.
Return any halved tablet to the blister pack and use within 1 day. The blister pack should be inserted back into the cardboard box.

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

Disposal: read package leaflet

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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAKOR 20 mg film-coated tablet for dogs

Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

VIRBAKOR 20 mg film-coated tablet for dogs

Benazepril hydrochloride

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

Marketing authorisation holder:
VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

Manufacturer for the batch release:
Laboratorios LICONSA, S.A
Avda. Miralcampo, 7, Pol. Ind. Miralcampo
Azuqueca de Henares, 19200 Guadalajara
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAKOR 20 mg film-coated tablet for dogs
Benazepril hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each divisible tablet contains:

Benazepril Hydrochloride .....20 mg
(equivalent to Benazepril 18.42 mg)

Excipients :
Titanium dioxide (E171) .....1.929 mg
Iron oxide yellow (E172).....0.117 mg
Iron oxide red (E172) .....0.014 mg
Iron oxide black (E172) .....0.004 mg

Beige, oblong, biconvex film-coated divisible tablets

4. INDICATION(S)

The 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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In double-blind clinical trials in dogs with congestive heart failure, the incidence of adverse reactions in treated dogs was lower than that observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In dogs 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Oral use.

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

The 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)	VIRBAKOR 20 mg Film-Coated Tablets	
	Standard dose	Double dose

>20 - 40	0.5 tablet	1 tablet
>40 – 80	1 tablet	2 tablets

The dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Do not store above 25°C. Store in a dry place.
Return any halved tablet to the blister pack and use within 1 day. The blister pack should be inserted back into the cardboard box.
Do not use after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for dogs
The efficacy and safety of the product has not been established in dogs 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
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.
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.

Use during pregnancy, lactation

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

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 “product name” (to be completed nationally) 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 product 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.

The product reduced erythrocyte counts in clinical healthy dogs when dosed at 150 mg/kg once daily for 12 months, but this effect was not observed at the recommended dose during clinical trials in dogs

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 local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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 remodeling effects (including pathological cardiac hypertrophy and degenerative renal changes).
The product causes long-lasting inhibition of plasma ACE activity in dogs, with more than 95% inhibition at peak effect and significant activity (>80% in dogs) persisting 24 hours after dosing.

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

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs, and therefore no adjustment of the dose of the product is necessary in the treatment of cases with renal insufficiency.

Carton box with 14 or 140 tablets.
Not all pack size may be marketed.
For animal treatment only – to be supplied only on veterinary prescription