

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**

**{NATURE/TYPE}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BANACEP vet 20 mg film-coated tablets for dogs  
Benazepril hydrochloride

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each divisible tablet contains:

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

**3. PHARMACEUTICAL FORM**

Film-coated divisible tablets

**4. PACKAGE SIZE**

14 tablets  
28 tablets  
56 tablets  
140 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Return any halved tablet to the blister pack and use within 1 day. The blister pack should be inserted into the cardboard box.

**8. WITHDRAWAL PERIOD**

Not applicable

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

[PL] Termin ważności (EXP)

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C. Store in the outer carton in order to protect from light.  
Store in a dry place

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

Any unused product or waste materials 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.

[PL] For animal treatment only. To be supplied only on veterinary prescription.  
Administration by a veterinary surgeon or under their direct responsibility

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

LABORATORIOS CALIER S.A  
Barcelonès, 26 - P.I. El Ramassar  
08520 Les Franqueses del Vallès (BCN)  
SPAIN

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 20634/4006

**17. MANUFACTURER'S BATCH NUMBER**

Batch

[PL] Nr serii (Lot)

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{NATURE/TYPE} BLISTER**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BANACEP vet 20 mg film-coated tablets for dogs  
Benazepril hydrochloride

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Laboratorios Calier, S.A.

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Batch

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## PACKAGE LEAFLET

BANACEP vet 20 mg film-coated tablets 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 and manufacturer  
LABORATORIOS CALIER S.A  
Barcelonès, 26 - P.I. El Ramassar  
08520 Les Franqueses del Vallès (BCN)  
SPAIN

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BANACEP vet 20 mg film-coated tablets for dogs  
Benazepril hydrochloride

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

Each divisible tablet contains:

Active substance:

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

### 4. INDICATION(S)

In dogs weighing more than 20 kg bw: Treatment of congestive heart failure.

### 5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to ACE inhibitors or to any ingredient of the product.

Do not use in any dog that has evidence of cardiac output failure, for example, due to aortic stenosis.

Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.

## 6. ADVERSE REACTIONS

At the start of the treatment, a decrease of the blood pressure and a transient increase of plasmatic concentrations of creatinine may occur.

On rare occasions (more than 1 but less than 10 animals in 10,000 animals), transient signs of hypotension, such as lethargy and ataxia may occur..

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.

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(S) AND METHOD OF ADMINISTRATION

For oral use.

The dose is 0.23 mg benazepril /kg bw per day, corresponding to 0.25 mg of Benazepril hydrochloride / kg bw per day. It should be given orally once daily, with or without food. It corresponds to 1/2 tablet per 20 to 40 kg and 1 tablet for dogs of more than 40 kg given according to the following regime:

Weight of dog (kg)	Number of tablets
>20 - 40	1/2 tablet
>40 - 80	1 tablet

Dosage may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon.

To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

None

## 10. WITHDRAWAL PERIOD

Not applicable

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children  
Do not store above 25°C. Store in the outer carton in order to protect from light. Store in a dry place

Return any halved tablet to the blister pack and use within 1 day. The blister pack should be inserted into the cardboard box.

Do not use after the expiry date stated on the carton after EXP

## **12. SPECIAL WARNING(S)**

### **Special precautions for use in animals**

No evidence of renal toxicity to benazepril has been observed in dogs. However, as is routine in cases of chronic renal insufficiency, it is recommended to monitor plasma creatinine, urea and erythrocyte counts during therapy.

### **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 ingestion by children seek medical advice immediately and show the package leaflet or the label to the doctor.

### **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 dogs. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses.

Do not use in breeding dogs.

### **Interaction with other medicaments and other forms of interaction**

Concomitant administration of potassium sparing diuretics may be considered. It is then recommended to regularly monitor potassium plasma levels.

The combination of this product with other anti-hypertensive agents (e.g. calcium channel blockers, b blockers or diuretics) anaesthetics or sedatives may lead to additive hypotensive effects. In man, the combination of ACE inhibitors and NSAIDs can lead to reduced anti-hypertensive efficacy or impaired renal function Therefore the concurrent use of NSAIDs or medications with hypotensive effect should be considered with care.

### **Overdose (symptoms, emergency procedures, antidotes)**

Transient reversible signs of hypotension may occur in cases of accidental overdose. Symptomatic treatment consists of intravenous infusion of warm isotonic saline.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials 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**

Box with 14, 28, 56 or 140 tablets. Not all pack size may be marketed.

[UK] To be supplied only on veterinary prescription  
POM-V

 10<sup>th</sup> October 2016