<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

10th October 2016