SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

BANACEP vet 20 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

Film-coated tablets
Beige oblong biconvex divisible tablets. The tablets can be divided into 2 equal parts.

4. CLINICAL PARTICULARS:

4.1 Target species:

Dogs

4.2 Indications for use, specifying target species:

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

4.3. Contraindications:

Do not use in cases 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.See also section 4.7.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness):

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.

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route:

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.

4.10 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.

4.11 Withdrawal period:

Not applicable

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ACE inhibitors, benazepril

ATCvet code: QC09AA07

5.1 Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed in vivo to benazeprilat. This active metabolite inhibits angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I into active angiotensin II. Therefore, benazeprilate inhibits all effects induced by angiotensin II, in particular, vasoconstriction of both arteries and veins and retention of sodium and water by the kidney. Benazepril hydrochloride causes long-lasting inhibition of plasma ACE in dogs, with significant inhibition persisting for 24 hours after a single dose.

In dogs with cardiac insufficiency, benazepril hydrochloride reduces the peripheral resistance, blood pressure of left ventricle and volume load on the heart.

5.2. Pharmacokinetic particulars

After oral administration, benazepril is rapidly absorbed from the gastrointestinal tract. One part of absorbed benazepril is hydrolyzed by hepatic enzymes to the active substance, benazeprilat; unchanged benazepril and hydrophilic metabolites account for the remainder. The absolute systemic bioavailability, calculated for oral benazepril versus intravenous benazepril is about 9%. Peak benazeprilat concentrations are achieved within about 2 hours, both in fasting and fed situations.
Benazepril and benazeprilat are extensively bound to plasma proteins. Repeated administration leads to slight accumulation of benazeprilat in plasma, steady state being achieved in less than 4 days.
In dogs, the major part of benazeprilat is rapidly eliminated, and it is excreted equally via hepatic and urinary routes.
After the administration of a single dose of the product (0.23 mg benazepril/ kg b.w.), peak benazeprilat concentrations (C_{max} of 40.9 ng/ml) were achieved within about 1.5 h (T_{max} of 1.5h), with AUC of 320.5 ng/ml.h and a half-life ($t_{1/2}$) of 12.4 h.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the nucleus :
Cellulose microcrystalline
Lactose monohydrate
Povidone
Maize starch
Silica colloidal anhydrous
Magnesium stearate

Excipients of the coating:
Iron oxide yellow (E-172)
Iron oxide red (E-172)
Iron oxide black (E-172)
Titanium dioxide (E-171)
Hypromellose
Macrogol 8000

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life of divisions of the tablets: 24 hours

6.4 Special precautions for storage:

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

6.5 Nature and composition of immediate packaging:

Blister made of clear film of PVC/PE/PVDC and aluminium film containing 14 tablets.
Box with:
- 1 blister (14 tablets)
- 2 blisters (28 tablets)
- 4 blisters (56 tablets)
- 10 blisters (140 tablets)

Not all pack size may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER S.A
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08520 Les Franqueses del Vallès (BCN)
SPAIN

8. MARKETING AUTHORISATION NUMBER

Vm 20634/4006

9. DATE OF THE FIRST AUTHORISATION

17 October 2011

10. DATE OF REVISION OF THE TEXT

October 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

 10 October 2016