

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 tablet contains:

Active substance:

Benazepril18.42 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 tablet.

Beige oblong biconvex film-coated divisible tablets.

4. CLINICAL PARTICULARS:

4.1 Target species:

Dogs.

4.2 Indications for use, specifying target species:

Dogs, weighing more than 20 kg bw: Treatment of congestive heart failure.

4.3 Contraindications:

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use during pregnancy or lactation. (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:

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.

Pregnant women should take special care to avoid accidental oral exposure, because angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

Special precautions for the protection of the environment

Not applicable.

Other precautions:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Undetermined frequency (cannot be estimated from the available data):	Vomiting Incoordination Fatigue Elevated creatinine*
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*In dogs with chronic kidney disease, 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.

In double-blind clinical trials in dogs with congestive heart failure, the veterinary medicinal product was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation

Do not use during pregnancy or lactation.

The safety of the veterinary medicinal 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.

4.8 Interaction with other medicaments and other forms of interaction

In dogs with congestive heart failure, the veterinary medicinal product has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal products without demonstrable adverse interactions.

In humans, the combination of ACE inhibitors and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired renal function. The combination of the veterinary medicinal product 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. Renal function and signs of hypotension (lethargy, weakness etc) should be monitored closely and treated as necessary.

Interactions with potassium preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. It is recommended to monitor plasma potassium levels when using the veterinary medicinal product in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

4.9 Amount(s) to be administered and administration route

Oral use.

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

This veterinary medicinal product should be administered 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)	Banacep Vet 20 mg Film-Coated tablet	
	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), if judged clinically necessary and advised by the veterinary surgeon.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

4.11 Withdrawal period(s)

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 its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of 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 pathological cardiac hypertrophy and degenerative renal changes).

The veterinary medicinal product causes long-lasting inhibition of plasma ACE activity, with more than 95% inhibition at peak effect and significant activity (>80% in dogs), persisting for 24 hours after dosing.

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

5.2 Pharmacokinetic particulars

After oral administration of benazepril hydrochloride, peak levels of benazepril are attained rapidly (T_{max} 0.5 hour in dogs) and decline quickly as the active substance is partially metabolized by liver enzymes to benazeprilat. The systemic bioavailability is

incomplete, (~13% in dogs) due to incomplete absorption (38% in dogs) and first pass metabolism.

In dogs, peak benazeprilat concentrations (C_{max} of 37.6 ng/ml after a dose of 0.5 mg/kg benazepril hydrochloride) are achieved with a T_{max} of 1.25 hours.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$ = 1.7 hours in dogs) represents elimination of free drug, while the terminal phase ($t_{1/2}$ = 19 hours in dogs) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%), and in tissues are found mainly in the liver and kidney.

There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs. Repeated administration of the veterinary medicinal product leads to slight bioaccumulation of benazeprilat ($R=1.47$ in dogs with 0.5 mg/kg), steady state being achieved within a few days (4 days in dogs).

Benazeprilat is excreted 54% via the biliary and 46% via the urinary route in dogs. The clearance of benazeprilat is not affected in dogs with impaired renal function and therefore no adjustment of the veterinary medicinal product dose is required in cases of renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Iron oxide yellow (E172)
Iron oxide red (E172)
Iron oxide black (E172)
Titanium dioxide (E171)
Cellulose microcrystalline
Lactose monohydrate
Povidone
Maize starch
Silica colloidal anhydrous
Magnesium stearate
Hypromellose
Macrogol 8000

6.2 Major incompatibilities

Not applicable

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life of tablet halves: 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 open blister space 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

Medicines should not be disposed of via wastewater.

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
C/Barcelones 26 (Pla del Ramassa)
08520 Les Franqueses del Valles
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 20634/5007

9. DATE OF THE FIRST AUTHORISATION

October 2011

10. DATE OF REVISION OF THE TEXT

June 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

11. CLASSIFICATION OF THE VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved 22 June 2024