**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard Box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BenazeVet 2.5 mg
tablets for cats and dogs
benazepril hydrochloride

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 2.5 mg benazepril hydrochloride

## 3. PHARMACEUTICAL FORM

Tablets

## 4. PACKAGE SIZE

28 tablets

## 5. TARGET SPECIES

Dogs and cats

## 6. INDICATION(S)

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

Oral use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Not applicable.

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

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Store in a dry place

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

Disposal: Read the 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4197

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

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

**Blister foil**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BenazeVet 2.5 mg
tablets for cats and dogs
benazepril hydrochloride

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Batch {number}

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

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET
## BenazeVet 2.5 mg tablets for cats and dogs

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

Marketing Authorisation Holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

Manufacturer responsible for batch release:
Elanco France S.A.S, 26 rue de la Chapelle, F-683330 Huningue, France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BenazeVet 2.5 mg tablets for cats and dogs
benazepril hydrochloride

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

Each tablet contains 2.5mg benazepril hydrochloride.
Beige, ovaloid, divisible tablets, scored on both sides.

## 4. INDICATION(S)

BenazeVet 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 and for reduction of proteinuria associated with chronic kidney disease in cats.

## 5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.
Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatraemia (low blood sodium levels) 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 or cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

## 6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.
In rare occasions diarrhoea and anorexia have been reported in dogs.

In dogs and cats 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.

The veterinary medicinal product may increase food consumption and body weight in cats. Vomiting, poor appetite, dehydration, lethargy and diarrhea have been reported on rare occasions in cats.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs and cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

This veterinary medicinal product should be given orally once daily, with or without food.
The duration of treatment is unlimited.
The product is flavoured and is taken voluntarily by most dogs and cats.

In dogs this veterinary medicinal 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)** | **BenazeVet 2.5 mg** | |
|---|---|---|
| | Standard dose | Double dose |
| 2.5-5 | 0.5 tablet | 1 tablet |
| >5-10 | 1 tablet | 2 tablets |

In dogs, the dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight if judged necessary and advised by the veterinary surgeon. Always follow the dosing instructions given by the veterinary surgeon.

In cats this veterinary medicinal product should be administered orally at a minimum dose of 0.5 mg (range 0.5-1.0) benazepril hydrochloride/kg body weight once daily according to the following table:

| Weight of cat (kg) | **BenazeVet 2.5 mg** |
|---|---|
| 2.5-5 | 1 tablet |
| >5-10 | 2 tablets |

## 9. ADVICE ON CORRECT ADMINISTRATION

For oral use only.
For animal treatment only.

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space, inserted back into the cardboard box and kept in a safe place out of reach of children.
Do not store above 25 °C.
Do not use after the expiry date stated on the blister or on the carton.

## 12. SPECIAL WARNING(S)

**Special warnings for each target species**
The efficacy and safety of the veterinary medicinal product has not been established in dogs and cats 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**
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.
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.

**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 or cats.

**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 the 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. 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 veterinary medicinal 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.

## 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 product should be disposed of in accordance with local requirements

## 14. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

## 15. OTHER INFORMATION

**Pharmacodynamic properties**
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 remodelling effects (including pathological cardiac hypertrophy and degenerative renal changes).
The veterinary medicinal product causes long-lasting inhibition of plasma ACE activity in dogs and cats, with more than 95% inhibition at peak effect and significant activity (>80% in dogs and >90% in cats) persisting 24 hours after dosing.

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

In cats with experimental renal insufficiency, the veterinary medicinal product normalized the elevated glomerular capillary pressure and reduced the systemic blood pressure. Reduction in glomerular hypertension may retard the progression of kidney disease by inhibition of further damage to the kidneys.
In a clinical trial in cats with chronic kidney disease, the product significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. The veterinary medicinal product also increased the appetite of the cats, particularly in more advanced cases.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs and 85% via the biliary and 15% via the urinary route in cats, and therefore no adjustment of the dose of the product is necessary in the treatment of cases with renal insufficiency.

**Package quantities:**
PVC/PE/PVdC-aluminium blisters with 14 tablets/blister.
Cardboard box with 2 blisters (28 tablets).

**Distributed by:**
Elanco Europe Limited
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA, UK

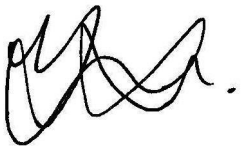
**On behalf of:**
IVC Evidensia

For product technical advice please telephone Elanco on 01256 353131, Option 1.

**Distribution Category**

| |
|---|
| POM-V |

**Marketing Authorisation Number**
Vm 00879/4197



Approved: 11 May 2024