PACKAGE LEAFLET

VETPRIL 5 mg film-coated tablet for dogs and cats
Benazepril hydrochloride [ES, PT, UK]

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

Marketing authorisation holder
Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer for the batch release
Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 5 mg film-coated tablet for dogs and cats
Benazepril hydrochloride [ES, PT, UK]

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tablet contains:
Active substance:
Benazepril .....4.6 mg
(equivalent to Benazepril Hydrochloride 5 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. INDICATIONS

In DOGS: weighing more than 5 kg bw: Treatment of congestive heart failure.
In CATS: Reduction of proteinuria associated with chronic kidney disease.

5. CONTRAINDICATIONS

Do not use in case 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.

6. ADVERSE REACTIONS

In double-blind clinical trials in dogs with congestive heart failure, benazepril was well tolerated with an incidence of adverse reactions lower than observed in placebo treated dogs.
A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.
In cats and dogs with chronic kidney disease, benazepril 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.
Benazepril may increase food consumption and body weight in cats.
Emesis, anorexia, dehydration, lethargy and diarrhoea have been reported in rare occasions in cats.
It is recommended to monitor plasma creatinine and erythrocyte counts during therapy.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

In dogs:
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 tablet per 20 kg given according to the following regime:

Weight of dog (kg)	Number of tablets
5 – 10	0.5
11 - 20	1

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

In cats:

The dose is 0.46 mg benazepril /kg bw per day, corresponding to 0.50 mg of Benazepril hydrochloride / kg bw per day. It should be given orally once daily, with or without food. It corresponds to 1 tablet per 10 kg given according to the following regime:

Weight of cat (kg)	Number of tablets
2.5 – 5.0	0.5
5.1 – 10.0	1

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children
Do not store above 25°C. 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 back into the cardboard box.
Do not use after the expiry date stated on the carton after EXP

12. SPECIAL WARNINGS

In dogs with congestive heart failure, benazepril 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 benazepril and other anti-hypertensive agents (e.g. calcium channel blockers, beta-adrenergic antagonists 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 benazepril in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

Benazepril reduced erythrocyte counts in normal cats when dosed at 10 mg/kg body weight once daily for 12 months and 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 cats or dogs.
Transient reversible hypotension may occur in cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

Do not use during pregnancy or lactation. The safety of benazepril has not been established in breeding, pregnant or lactating dogs and cats. Benazepril reduced ovary/oviduct weights in cats when administered daily at 10 mg/kg body weight for 52 weeks. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally nontoxic doses.

No evidence of renal toxicity to benazepril has been observed (in dogs or cats) during clinical trials, however, as is routine in cases of chronic kidney disease, it is recommended to monitor plasma creatinine, urea and erythrocyte counts during therapy.

The efficacy and safety of benazepril has not been established in dogs and cats below 2.5 kg body weight.

USER WARNINGS

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 angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

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 products 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 or 140 tablets.
Not all pack size may be marketed.

To be supplied only on veterinary prescription

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 5 mg film-coated tablet for dogs and cats
Benazepril hydrochloride [ES, PT, UK]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
Active substance:
Benazepril 4.6 mg
(equivalent to Benazepril Hydrochloride 5 mg)

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PACKAGE SIZE

14 tablets
140 tablets

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

In DOGS: weighing more than 5 kg bw: Treatment of congestive heart failure.
In CATS: Reduction of proteinuria associated with chronic kidney disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should take special care to avoid accidental oral exposure. See package leaflet for full user warnings
Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
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 back into the cardboard box.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
SPAIN

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 5 mg film-coated tablet for dogs and cats
Benazepril hydrochloride [ES, PT, UK]

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.