<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 20 mg film-coated tablets for dogs
Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each divisible tablet contains:

Benazepril .....18.42 mg

(equivalent to Benazepril Hydrochloride 20 mg)

3. PHARMACEUTICAL FORM

Film-coated 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.
Any unused divided tablet portion should be returned into the blister, kept within the outer carton.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life of halved tablets: 24 hours

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

Dispose of waste material 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed by:

16. MARKETING AUTHORISATION NUMBER

Vm 32509/4020

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE} BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 20 mg film-coated tablets for dogs
Benazepril hydrochloride

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.

PACKAGE LEAFLET

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

Manufacturer for the batch release
LABORATORIUM SANITATIS, S.L.
C/Leonardo da Vinci, 11 (Parque Tecnológico de Álava) Miñano
01510 Álava SPAIN

Distributed by:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETPRIL 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

Beige oblong biconvex film-coated divisible tablets

4. INDICATION(S)

The veterinary medicinal product is prescribed by the veterinary surgeon for the treatment of congestive heart failure in dogs weighing more than 20 kg.

5. CONTRAINDICATIONS

Do not use in cases of known 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 in pregnancy or lactation in dogs because the safety of Benazepril Hydrochloride has not been established during pregnancy or lactation in this species.

6. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting, incoordination or fatigue during treatment.
In dogs 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.

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

Oral use

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

The 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)	Benazepril hydrochloride 20 mg film-Coated Tablets	
	Standard dose	Double dose
>20 - 40	0.5 tablet	1 tablet
>40 – 80	1 tablet	2 tablets

In dogs with congestive heart failure, the dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), benazepril hydrochloride/kg body weight if judged clinically necessary and advised by the veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

Return any halved tablet to the blister pack and use within 1 day. The blister pack should be inserted back into the cardboard box.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the blister in the outer carton in order to protect from light and moisture.
Any unused divided tablet portion should be returned into the blister, kept within the outer carton..

Do not use this veterinary medicinal product after the expiry date which is stated stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.
Shelf-life of halved tablets: 24 hours.

12. SPECIAL WARNING(S)

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
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 oral ingestion, seek medical advice immediately and show the label or the package leaflet to the physician.

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.

Interaction with other medicaments 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 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.

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 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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2020

15. OTHER INFORMATION

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

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

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

Box with 14, 28, 56 or 140 tablets. Not all pack sizes may be marketed.
For animal treatment only – to be supplied only on veterinary prescription

Approved 17 March 2020