PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Benazapet 5 mg tablets for cats and dogs
Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each divisible tablet contains 5 mg benazepril hydrochloride

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

56 tablets

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be given orally once daily.
Daily dose for dogs: 0.25-0.5 mg benazepril hydrochloride/kg body weight
Daily dose for cats: 0.5-1.0 mg benazepril hydrochloride/kg body weight.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}
In-use shelf-life of tablet halves is 2 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Return half tablet to blister pocket and store in original carton, use at next administration.

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
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Benazapet 5 mg Tablets for cats and dogs
Benazepril Hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
MiPet Benazapet 5 mg tablets for cats and dogs
MiPet Benazapet 20 mg tablets for 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
United Kingdom

Manufacturer responsible for batch release:
Elanco France S.A.S, 26 Rue de la Chapelle, F-68330 Huningue, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Benazapet 5 mg tablets for cats and dogs
MiPet Benazapet 20 mg tablets for dogs

Benazepril hydrochloride

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

Beige to light brown, ovaloid divisible tablets scored on both sides:
5 mg benazepril hydrochloride (MiPet Benazapet 5 mg tablets)
20 mg benazepril hydrochloride (MiPet Benazapet 20 mg tablets)

The tablets can be divided into halves.

4. INDICATION(S)

MiPet Benazapet 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 case of hypersensitivity to the active substance benazepril hydrochloride or to any of the excipients. Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatremia 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

In double-blind clinical trials in dogs with congestive heart failure, MiPet Benazepet 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.
On rare occasions diarrhoea and anorexia have been reported in dogs.

In cats and dogs with chronic kidney disease, MiPet Benazapet 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.

MiPet Benazapet may increase food consumption and body weight in cats. Vomiting, poor appetite, dehydration, lethargy and diarrhoea 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 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(S) AND METHOD OF ADMINISTRATION

MiPet Benazapet should be given orally once daily, with or without food. The duration of treatment is unlimited. MiPet Benazapet tablets are flavoured and are taken voluntarily by most dogs and cats. In dogs MiPet Benazapet 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)	**MiPet Benazapet 5 mg**	
	Standard dose	Double dose
>5-10	0.5 tablet	1 tablet
>10-20	1 tablet	2 tablets
>20-40	-	-
>40-80	-	-

Weight of dog (kg)	**MiPet Benazapet 20 mg**	
	Standard dose	Double dose
>5-10	-	-
>10-20	-	-
>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 (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 MiPet Benazapet 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)	**MiPet Benazapet 5 mg**
2.5-5	0.5 tablet
>5-10	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

For oral use only.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Return half tablet to blister pocket and store in original carton, use at next administration.
Tablet halves should be used within 2 days.
MiPet Benazapet 5 mg: do not store above 25 °C.
MiPet Benazapet 20 mg: This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after ‘EXP’. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for dogs and cats
The efficacy and safety of MiPet Benazapet has not been established in dogs and cats below 2.5 kg body weight. No evidence of renal toxicity to MiPet Benazapet has been observed in dogs during clinical trials. The biliary excretion benazeprilat means there is little risk of bioaccumulation in dogs or cats with impaired renal function.

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.

Use during pregnancy, lactation
The safety of MiPet Benazapet has not been established in breeding, pregnant or lactating dogs or cats.

Pregnancy:
Do not use during pregnancy or lactation.
Laboratory studies in rats have shown evidence of embryotoxic effects (foetal urinary tract malformation) at maternally non-toxic doses. Benazepril reduced ovary/oviduct weights in cats when administered daily at 10 mg/kg body weight for 52 weeks

Interactions
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
In dogs with congestive heart failure, MiPet Benazapet 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 MiPet Benazapet 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 MiPet Benazapet in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose
MiPet Benazapet 5 mg tablets 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 (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. 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).
MiPet Benazapet 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.

MiPet Benazapet reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.
In cats with experimental renal insufficiency, MiPet Benazapet 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, MiPet Benazapet significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. MiPet Benazapet 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 MiPet Benazapet is necessary in the treatment of cases with renal insufficiency.

Package quantities:
Aluminium/aluminium blisters with 14 tablets/blister.
Cardboard box with:
- 2 blisters (28 tablets) MiPet Benazapet 20 mg
- 4 blisters (56 tablets) MiPet Benazapet 5 mg

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local Representative:
MiGroup
12b Progress Way
Mid-Suffolk Business Park
Eye
Suffolk
IP23 7HU
products@cvsvets.com

Distribution Category
To be supplied only on veterinary prescription.

Marketing Authorisation Numbers
MiPet Benazapet 5 mg tablets for cats and dogs: Vm 00879/4002
MiPet Benazapet 20 mg tablets for dogs: Vm 00879/4001

Gavin Hall

Approved: 12 June 2024