<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ARIXIL vet 5 mg film-coated tablet for dogs and cats

Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
Benazepril Hydrochloride 5 mg
(equivalent to Benazepril 4.6 mg)

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

14 tablets
28 tablets
56 tablets
140 tablets

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

DOGS: Treatment of congestive heart failure.
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

Disposal: read 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 SIGHTAND REACHOF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36547/4007

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ARIXIL vet 5 mg film-coated tablet for dogs and cats

Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

ARIXIL vet5 mg film-coated tablet for dogs and cats

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

Marketing authorisation holder

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
Spain

Manufacturer for the batch release

Industrial Veterinaria, S.A.
Esmeralda 19,
E-08950 Esplugues de Llobregat (Barcelona)
SPAIN

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
GERMANY

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ARIXIL vet 5 mg film-coated tablet for dogs and cats
Benazepril hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each film-coated tablet contains:
Active substance:
Benazepril Hydrochloride.....5 mg
(equivalent to Benazepril 4.6 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. INDICATION(S)

DOGS: Treatment of congestive heart failure.
CATS: Reduction of proteinuria associated with chronic kidney disease.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in cases of hypotension, hypovolaemia, hyponatraemia or acute renal failure.
Do not use during pregnancy or lactation (see section 12)

6. ADVERSE REACTIONS

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.
A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.
In cats and dogs with chronic kidney disease, the veterinary medicinal product 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.
The veterinary medicinal product may increase food consumption and body weight in cats.
Emesis, anorexia, dehydration, lethargy and diarrhea have been reported in 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 AND METHOD OF ADMINISTRATION

For oral use.
In dogs:
It should be given orally once daily, with or without food. The dose is 0.23 mg benazepril /kg bw per day, corresponding to 0.25 mg of Benazepril hydrochloride / kg bw per day, according to the following table:

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

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

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

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(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach 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 this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals
No evidence of renal toxicity to the veterinary medicinal product 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 the veterinary medicinal product has not been established in dogs and cats below 2.5 kg body weight.

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 angiotensin converting enzyme (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 and lactation. The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating dogs and cats. The veterinary medicinal product 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. Do not use in breeding animals.

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 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 the veterinary medicinal product in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

Overdose (symptoms, emergency procedures, antidotes) if necessary
The veterinary medicinal product 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.

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

November 2023

15. OTHER INFORMATION

Box with 14, 28, 56 or 140 tablets.
Not all pack size may be marketed.

To be supplied only on veterinary prescription.

Approved: 10 May 2024