<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ARIXIL vet 20 mg film-coated tablet for dogs

Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
Benazepril hydrochloride 20 mg
(equivalent to Benazepril 18.42 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)

Dogs: Treatment of congestive heart failure.

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. Store in the outer carton in order to 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 SIGHT AND REACH OF 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(S)

Vm 36547/4008

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE} BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ARIXIL vet 20 mg film-coated tablet for dogs

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 vet 20 mg film-coated tablet 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

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 20 mg film-coated tablet for dogs

Benazepril hydrochloride

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

Each film-coated tablet contains:
Active substance:
Benazepril Hydrochloride .....20 mg
(equivalent to Benazepril 18.42 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.

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 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 in treated dogs lower than that observed in placebo-treated dogs.

A small number of dogs may exhibit transient vomiting, incoordination or signs of fatigue.

In 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 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, 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

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

For oral use.
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
>20 - 40	1/2 tablet
>40 - 80	1 tablet

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Do not store above 25°C. Store in the outer carton in order to 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 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 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 enzymes (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 veterinary medicinal product has not been established in breeding, pregnant or lactating dogs. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally non-toxic doses. Do not use in breeding dogs.

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, pimobendane 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 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. 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 product in combination with a potassium sparing diuretic because of the risk of hyperkalaemia.

Overdose (symptoms, emergency procedures, antidotes)
The veterinary medicinal product reduced erythrocyte counts 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 28 November 2023