PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actikor 5 mg Film-coated Tablets for Dogs

Benazepril Hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each film-coated tablet contains benazepril 4.6 mg (equivalent to 5 mg of benazepril hydrochloride)

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

14 tablets (1x14)
28 tablets (2x14)
56 tablets (4x14)
84 tablets (6x14)
140 tablets (10x14)

5. TARGET SPECIES

Dog

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
In case of using halved tablets: Return any remaining half tablet to the opened blister pocket. Use the remaining half tablet for the next administration.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
B-8020, Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4006

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alu-Alu Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actikor 5 mg Film-coated Tablets for Dogs

Benazepril Hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:
Actikor 5 mg Film-coated 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:
Ecuphar NV
Legeweg 157-i
B-8020, Oostkamp
Belgium

Manufacturer responsible for batch release:
Ecuphar NV
Legeweg 157-i
B-8020, Oostkamp
Belgium

or

Accord Healthcare Limited
Sage House, 319, Pinner Road, North Harrow, Middlesex HA1 4HF,
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actikor 5 mg Film-coated Tablets for Dogs

Benazepril Hydrochloride

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

Each film-coated tablet contains benazepril 4.6 mg (equivalent to 5 mg of benazepril hydrochloride).

Yellow coloured, oval, biconvex, film-coated tablets with a breakline on one side and plain on the other side.

The tablets can be divided into two equal parts.

4. INDICATION(S)

Dogs weighing more than 5 kg:
Treatment of congestive heart failure associated with, in particular, dilated cardiomyopathy or mitral insufficiency.

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

6. ADVERSE REACTIONS

In double-blind clinical trials in dogs with congestive heart failure, the incidence of adverse reactions in treated dogs was 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 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.

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

7. TARGET SPECIES

Dog.

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

For oral use.

The therapeutic oral dose is 0.25 mg benazepril hydrochloride/kg body weight once daily, with or without food according to the following dose regime:

Dogs weighing 5-10 kg: ½ Actikor 5 mg tablet.
Dogs weighing 11-20 kg: 1 Actikor 5 mg tablet.
Dogs weighing 21-40 kg: ½ Actikor 20 mg tablet.
Dogs weighing 41-80 kg: 1 Actikor 20 mg tablet.

The dose may be doubled (0.5 mg benazepril hydrochloride/kg body weight) still administered once daily, if judged clinically necessary and advised by the veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

For animal use.
For oral administration.

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30 °C.
In case of using halved tablets: Return any remaining half tablet to the opened blister pocket. Use the remaining half tablet for the next administration.
Do not use this veterinary medicinal product after the expiry date stated on the blister and carton after EXP. The expiry date refers to the last day of the 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
ACE inhibitors have been found to affect the unborn child during pregnancy in humans. Pregnant women should take special care to avoid accidental exposure, including hand-to-mouth contact.
Wash hands after use.
Benazepril may cause hypotension after oral ingestion.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy and lactation:
Studies in laboratory animals (rats) have shown embryotoxic effects of benazepril at non-maternotoxic doses (malformations of the foetal urinary system). Benazepril administered to cats at a daily dose of 10 mg/kg for 52 weeks resulted in the reduction of ovary/oviduct weights.
In humans ACE inhibitors have been found to be teratogenic during pregnancy.
Do not use in breeding, pregnant or lactating dogs as the safety of the product in these animals has not been tested.

Interaction with other medicinal products and other forms of interaction:
None known in dogs.
In dogs with heart failure, Benazepril hydrochloride has been given in combination with digoxin, diuretics and anti-arrythmic drugs without demonstrable adverse interactions. In human, the combination of ACE inhibitors and 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 closely monitored 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 as life threatening reactions are a possibility.

Overdose (symptoms, emergency procedures, antidotes):
The 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 dogs.
Transient reversible hypotension may occur in cases of accidental overdosage. 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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Tablets are presented in aluminium foil blister packs of 14, 28, 56, 84 and 140 tablets.
Not all pack sizes may be marketed.

For animal treatment only.
To be supplied only on veterinary prescription.

Approved: 22 December 2016