ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexepril 2.5mg Film-coated tablet for dogs (BE & IE)
Bexepril 2.5mg Film-coated tablet for dogs (BG, CY, CZ, DK, EL, ES, HU, LU, NL, NO, PT, RO, SI, SK & UK)
Sirdis 2.5mg Film-coated tablet for dogs (IT)

Bexepril 2.5mg Film-coated tablets for dogs (PL)
Bexepril 2.5 Film-coated tablet for dogs (FR)
Bexepril 2.5mg Film-coated tablets for dogs, Benazeprilhydochlorid (AT)
Benadog 2.5 mg Film-coated tablets for dogs, Benzeprilhydochlorid (DE)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One Grilled meat flavoured tablet contains 2.3 mg benazepril (equivalent to Benazepril Hydrochloride 2.5 mg)

3. PHARMACEUTICAL FORM

Film coated tablet

4. PACKAGE SIZE

Blisters: 14, 28, 42, 56, 70, 84, 98, 112, 128, 140, 154, 168, 182, 196, 210, 224, 238, 252, 266, 280, 294, 308, 350, 392, 448, 546, 602, 700, 798, 896, 994 and 1008 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration
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 25°C. Store in original package in order to protect from light.

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

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Bexepril 2.5mg Film-coated tablet for dogs (BE & IE)

Bexepril 2.5mg Film-coated tablet for dogs (BG, CY, CZ, DK, EL, ES, HU, LU, NL, NO, PT, RO, SI, SK & UK)

Sirdis 2.5mg Film-coated tablet for dogs (IT)

Bexepril 2.5mg Film-coated tablets for dogs (PL)

Bexepril 2.5 Film-coated tablet for dogs (FR)

Bexepril 2.5mg Film-coated tablet for dogs, Benazeprilhydochlorid (AT)

Benadog 2.5 mg Film-coated tablets for dogs, Benzeprilhydochlorid (DE)

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

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexepril 2.5mg Film-coated tablet for dogs (BE & IE)

Bexepril 2.5mg Film-coated tablet for dogs (BG, CY, CZ, DK, EL, ES, HU, LU, NL, NO, PT, RO, SI, SK & UK)

Sirdis 2.5mg Film-coated tablet for dogs (IT)

Bexepril 2.5mg Film-coated tablets for dogs (PL)

Bexepril 2.5 Film-coated tablet for dogs (FR)

Bexepril 2.5mg Film-coated tablets for dogs, Benazeprilhydochlorid (AT)

Benadog 2.5 mg Film-coated tablets for dogs, Benzeprilhydochlorid (DE)

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

Active substance:

One grilled meat flavoured tablet contains 2.3 mg benazepril (equivalent to Benazepril hydrochloride 2.5mg)

Titanium Dioxide (E171) : **0.5mg**

A white round biconvex tablet with break line on one side.

4. INDICATION(S)

In dogs weighing more than 5 kg:

Treatment of congestive heart failure associated with, in particular, dilated cardiomyopathy and/or mitral insufficiency.

5. CONTRAINDICATIONS

Do not use in any dog that has evidence of cardiac output failure due, for example, to aortic stenosis.

Do not use in animals known to be hypersensitive to the active substance or to any of the excipient(s). See Section 12.

6. ADVERSE REACTIONS

On rare occasions, transient signs of hypotension, such as lethargy and ataxia, may occur.
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

For oral use only.
The recommended oral dose is 0.23 mg benazepril per kg bodyweight per day, equivalent to 0.25 mg of benazepril hydrochloride per kg bodyweight per day, as one administration. The dose may be doubled, still administered once daily, if judged clinically necessary and advised by the veterinary surgeon.
Benazepril should be given orally once daily, with or without food. The duration of treatment is unlimited.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date stated which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the cardboard box. This unused half tablet must be used within 24 hours. Store in original package in order to protect from light.

12. SPECIAL WARNING(S)

Use during pregnancy, lactation or lay

Do not use in pregnant or nursing bitches or in bitches intended for breeding.
Studies in laboratory animals have shown embryotoxic effects of benazepril at non-maternotoxic doses (urinary tract abnormalities in the foetus). The safety of the product has not been assessed during pregnancy and lactation in dogs.

Laboratory studies in rats and observations in humans have produced evidence of teratogenic effects.

Interaction with other medicinal products and other forms of interaction

In dogs with heart failure, Benazepril has been given in combination with digoxin, diuretics and anti-arrythmic drugs without demonstrable adverse interactions.

In man, the combination of ACE inhibitors and 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, P-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 benazepril in combination with a potassium sparing diuretic as life-threatening reactions are possible. As with other ACE Inhibitors, the use of hypotensive medicinal products or anaesthetics with a hypotensive effect may add to the anti-hypertensive effect of benazepril.

Overdose (symptoms, emergency procedures, antidotes)

In normal dogs, overdosage up to 200-fold was asymptomatic.

Transient reversible hypotension may occur in cases of accidental overdosage. Therapy should consist of intravenous infusion of warm isotonic saline.

Special precautions for use in animals

No evidence of renal toxicity to the product has been observed in dogs during clinical trials. However, as is routine in cases of renal insufficiency, it is recommended to monitor plasma creatinine and urea during therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental oral ingestion, seek medical advice 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.

Wash hands after use.

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

15. OTHER INFORMATION

Pack sizes: 14, 28, 42, 56, 70, 84, 98, 112, 128, 140, 154, 168, 182, 196, 210, 224, 238, 252, 266, 280, 294, 308, 350, 392, 448, 546, 602, 700, 798, 896, 994 and 1008 Tablets

Not all pack sizes may be marketed.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE} Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Bexepril 2.5mg Film-coated tablet for dogs, Benazeprilhydochlorid (AT)

Benadog 2.5 mg Film-coated tablets for dogs, Benzeprilhydochlorid (DE)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.