ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nelio 5 mg tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substance:
Benazepril (as hydrochloride).....4,60 mg
(equivalent to benazepril hydrochloride..... 5,00 mg)

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
50 tablets
100 tablets
200 tablets
500 tablets

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}

Shelf-life of divisions of the tablets: 72 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C
Store in original package in order to protect from moisture.
Any part-used tablet should be returned to the opened blister and used within 72 hours.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBER

Vm 14966/3018
Vm 14966/5019

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nelio

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg of benazepril hydrochloride

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nelio 5 mg tablet for cats

2. Composition

Each tablet contains:

Active substance:
Benazepril (as hydrochloride).....4,60 mg
(equivalent to benazepril hydrochloride..... 5,00 mg)
Clover shaped scored beige tablet, divisible into halves or quarters.

3. Target species

Cats.

4. Indications for use

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 hypotension (low blood pressure), hypovolemia (low blood volume), hyponatraemia (low blood sodium levels) or acute renal failure.
Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use during pregnancy or lactation (see section: Special warnings).

6. Special warnings

Special precautions for safe use in the target species:
Efficacy and safety of benazepril have not been established in cats of weight less than 2.5 kg.
No evidence of renal toxicity to the veterinary medicinal product has been observed in 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans. Pregnant women should take special care to avoid accidental oral exposure.
Wash hands after use.
In case of accidental oral ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating cats.
Benazepril reduced ovary / oviduct weights in cats when administered daily at 10 mg / kg for 52 weeks. Embryotoxic effects (foetal urinary tract malformation) were seen in trials with laboratory animals (rats) at maternally nontoxic doses.
Do not use during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.
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 the veterinary medicinal product and other anti-hypertensive agents (e.g. calcium channel blockers, ß-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 the veterinary medicinal product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose:
Transient reversible hypotension (low blood pressure) may occur in case of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Diarrhoea, Emesis (vomiting), Anorexia, Dehydration, Lethargy
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated creatinine[1]
Undetermined frequency (cannot be estimated from the available data):
Increased appetite, Weight gain

[1]At the start of therapy, in cats with chronic kidney disease. 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 therefore is not necessarily a reason to stop therapy in the absence of other signs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.
The veterinary medicinal product should be given orally once daily, with or without food. The duration of treatment is unlimited.
The veterinary medicinal product tablets are flavoured and are taken voluntarily by most cats.

In cats the veterinary medicinal product 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:

Cat weight (kg)	Number of tablets
2.5 – 5.0	0.5
>5.0 – 10.0	1

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

The tablets are flavoured and may be taken spontaneously by cats but can also be administered directly into the cat's mouth or be given with food if necessary

In case of use of half tablets: Put the remaining half of the tablet back into the blister pocket and use for the next administration.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Store in original package in order to protect from moisture.
Shelf-life of divisions of the tablets: 72 hours.
Any part-used tablet should be returned to the opened blister and used within 72 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and outer carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 14966/3018
Vm 14966/5019

Pack sizes:
Box with 1 strip of 10 tablets
Box with 2 strips of 10 tablets
Box with 3 strips of 10 tablets
Box with 5 strips of 10 tablets
Box with 10 strips of 10 tablets
Box with 20 strips of 10 tablets
Box with 50 strips of 10 tablets

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: +800 35 22 11 51

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
FRANCE

17. Other information

Pharmacodynamics:
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).
The veterinary medicinal product causes long-lasting inhibition of plasma ACE activity in cats, with more than 95% inhibition at peak effect and significant activity (>90%) persisting 24 hours after dosing.
In cats with experimental renal insufficiency, the veterinary medicinal product 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, the veterinary medicinal product significantly reduced protein loss in the urine; this effect is probably mediated via reduced glomerular hypertension and beneficial effects on the glomerular basement membrane. The veterinary medicinal product also increased the appetite of the cats, particularly in more advanced cases.
In contrast with other ACE inhibitors, benazeprilat is excreted 85% via the biliary and 15% via the urinary route, and therefore no adjustment of the dose of the veterinary medicinal product is necessary in the treatment of cases with renal insufficiency.

Gavin Hall
Approved: 01 October 2025