

Veterinary Medicinal product

NELIO 2.5 mg TABLET FOR CATS

PART IB

A - LABELLING

Pharmaceutical form

Tablet

Veterinary Medicinal product

NELIO 2.5 mg TABLET FOR CATS

PART IB

A – LABELLING – “OUTER PACKAGE”

Pharmaceutical form

Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NELIO 2.5 mg TABLET FOR CATS
Benazepril hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benazepril hydrochloride2.5 mg

3. PHARMACEUTICAL FORM

Tablet
Oblong scored beige tablet, divisible into halves

4. PACKAGE SIZE

Box with 1 strip of 10 tablets
Box with 2 strips of 10 tablets
Box with 5 strips of 10 tablets
Box with 10 strips of 10 tablets
Box with 14 strips of 10 tablets
Box with 18 strips of 10 tablets

5. TARGET SPECIES

Cats.

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: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Store in original package.
Any part-used tablet should be returned to the opened blister and used within 24 hours

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4107

17. MANUFACTURER’S BATCH NUMBER

Batch:

Veterinary Medicinal product

NELIO 2.5 mg TABLET FOR CATS

PART IB

A – LABELLING – BLISTER

Pharmaceutical form

Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NELIO 2.5 mg TABLET FOR CATS
Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER



3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Veterinary Medicinal product

NELIO 2.5 mg TABLET FOR CATS

PART IB

B – PACKAGE LEAFLET

Pharmaceutical form

Tablet

PACKAGE LEAFLET

NELIO 2.5 mg TABLET FOR 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:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NELIO 2.5 mg TABLET FOR CATS
Benazepril hydrochloride

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

Each tablet contains 2.5 mg of benazepril hydrochloride

4. INDICATION(S)

The product belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It is prescribed by the veterinary surgeon for reduction of proteinuria associated with chronic kidney disease in cats.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance benazepril hydrochloride or to any ingredient of the tablets.

Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume) or acute renal failure.

Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.

Do not use in pregnant or lactating cats because the safety of benazepril hydrochloride has not been established during pregnancy or lactation in these species.

6. ADVERSE REACTIONS

In cats with chronic kidney disease there may be a moderate increase in levels of creatinine, an indicator of kidney function, in the blood. This is likely due to the effect of the medication in reducing the blood pressure within the kidney and is therefore not necessarily a reason for treatment to be stopped, unless the animal is showing other adverse reactions.

The product may increase food consumption and body weight in cats.

Vomiting, poor appetite, dehydration, lethargy and diarrhoea have been reported on rare occasions in cats.

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

7. TARGET SPECIES

Cats.

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

The product should be given orally once daily, with or without food. The duration of treatment is unlimited.

The product tablets are flavoured and are taken voluntarily by most cats.

In cats "*product name*" (*to be completed nationally*) 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	1
>5. – 10	2

9. ADVICE ON CORRECT ADMINISTRATION

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.

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 original package.

Any part-used tablet should be returned to the opened blister and used within 24 hours.

Do not use the veterinary medicinal product after the expiry date stated on the blister and outer carton.

12. SPECIAL WARNING(S)

Special warnings for dogs and cats

The efficacy and safety of the product has not been established in cats below 2.5 kg body weight.

Special precautions for use in animals

In cases of chronic kidney disease, your veterinarian will check the hydration status of your pet before starting therapy, and may recommend that regular blood tests are carried out during therapy in order to monitor plasma creatinine concentrations and blood erythrocyte counts.

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

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.

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.

Use during pregnancy and lactation

Do not use during pregnancy or lactation. The safety of the product has not been established in breeding, pregnant or lactating dogs or cats.

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 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.

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 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.

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

October 2022

15. OTHER INFORMATION

Pack sizes:

Box with 1 strip of 10 tablets
Box with 2 strips of 10 tablets
Box with 5 strips of 10 tablets
Box with 10 strips of 10 tablets
Box with 14 strips of 10 tablets
Box with 18 strips of 10 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representative:

Pharmacodynamic properties

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat.

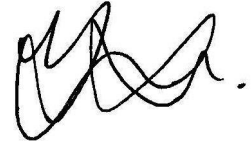
Benazeprilat is a highly potent and selective inhibitor of the angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I to active angiotensin II and thereby also reducing synthesis of aldosterone. Therefore, it blocks effects mediated by angiotensin II and aldosterone, 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 product causes long-lasting inhibition of plasma ACE activity in cats, with more than 95% inhibition at peak effect and significant activity (>90% in cats) persisting 24 hours after dosing.

In cats with experimental renal insufficiency, the 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 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 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 in cats, and therefore no adjustment of the dose of the product is necessary in the treatment of cases with renal insufficiency.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 12 October 2022