

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
50 tablets
100 tablets
250 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before 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 NUMBERS

Vm 14966/3019

Vm 14966/5020

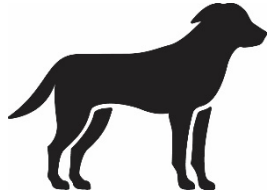
15. BATCH NUMBER

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}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nelio 5 mg Tablet for Dogs

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

Dogs

4. Indications for use

The product belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It is prescribed by the veterinary surgeon for the treatment of congestive heart failure in dogs.

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), 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 in pregnant or lactating dogs because the safety of benazepril hydrochloride has not been established during pregnancy or lactation.

6. Special warnings

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

Special precautions for safe use in the target species:

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.

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.

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.

Major incompatibilities:

None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting ¹ Incoordination ¹ Fatigue ¹ Elevated creatinine ²
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¹Transient

²At 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.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 dogs.

Dogs:

The product should be administered orally at a minimum dose of 0.25 mg (range 0.25-0.5) benazepril hydrochloride/kg body weight once daily, according to the following table:

Weight of dog (kg)	Standard dose	Double dose
2.5-5	0.25 tablet	0.5 tablet
>5-10	0.5 tablet	1 tablet
>10-15	0.75 tablet	1.5 tablets
>15-20	1 tablet	2 tablets

In dogs with congestive heart failure, the dose may be doubled, still administered once daily, to a minimum dose of 0.5 mg/kg (range 0.5-1.0), if judged clinically necessary and advised by the veterinary surgeon. Always follow the dosing instructions given by the veterinary surgeon.

9. Advice on correct administration

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

In case of use of quarters or half tablets: Put the remaining quantity 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 the veterinary medicinal product after the expiry date 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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/3019

Vm 14966/5020

Pack sizes:

Cardboard box with 1 blister strip of 10 tablets

Cardboard box with 5 blister strips of 10 tablets

Cardboard box with 10 blister strips of 10 tablets

Cardboard box with 25 blister 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: 00800 35 22 11 51

Email for the reporting of adverse events: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall
Approved: 01 October 2025