Veterinary Medicinal product

NELIO 20 MG TABLET FOR DOGS

PART IB

A - LABELLING

Pharmaceutical form

Tablet

Veterinary Medicinal product

NELIO 20 MG TABLET FOR DOGS

PART IB

A – LABELLING – "OUTER PACKAGE"

Pharmaceutical form

Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nelio 20 mg Tablet for Dogs
Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Benazepril hydrochloride .....20 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10 tablets
50 tablets
100 tablets
140 tablets
180 tablets

5. TARGET SPECIES

Dogs

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

11. SPECIAL STORAGE CONDITIONS

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.

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(S)

Vm 15052/4108

17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal product

NELIO 20 MG TABLET FOR DOGS

PART IB

A – LABELLING – BLISTER

Pharmaceutical form

Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nelio 20 mg Tablet for Dogs

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 20 MG TABLET FOR DOGS

PART IB

B – PACKAGE LEAFLET

Pharmaceutical form

Tablet

PACKAGE LEAFLET

NELIO 20 MG TABLET 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:
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 20 mg Tablet for Dogs

Benazepril hydrochloride

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

Each tablet contains 20 mg of benazepril hydrochloride

Clover shaped scored beige tablet, divisible into halves or quarters.

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 the treatment of congestive heart failure in dogs.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypotension (low blood pressure), hypovolaemia (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. ADVERSE REACTIONS

Some dogs with congestive heart failure may exhibit vomiting or fatigue during treatment.
In dogs 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.

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

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 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
>20-40	0.5 tablet	1 tablet
>40-60	0.75 tablet	1 ½ tablets
>60-80	1 tablet	2 tablet

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 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 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 WARNING(S)

Special warnings for dogs
The efficacy and safety of this product has not been established in dogs 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, lactation or lay
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 dogs with congestive heart failure, this product has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic products without evidence of associated adverse reactions.

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 this 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 this product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose (symptoms, emergency procedures, antidotes), if necessary
Transient reversible hypotension (low blood pressure) may occur in cases 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:
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 14 blister strips of 10 tablets
Cardboard box with 18 blister 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.

Pharmacodynamic properties

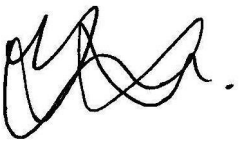
Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat.

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).

This product causes long-lasting inhibition of plasma ACE activity in dogs, with more than 95% inhibition at peak effect and significant activity (>80%) persisting 24 hours after dosing.

This product reduces the blood pressure and volume load on the heart in dogs with congestive heart failure.

In contrast with other ACE inhibitors, benazeprilat is excreted equally by both biliary and urinary routes in dogs, and therefore no adjustment of the dose of this product is necessary in the treatment of cases with renal insufficiency.



Approved: 12 October 2022