

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NELIO 5 COMPRIME POUR CHATS : FR

\* NELIO 5 MG TABLET FOR CATS: AT-BE-ES-GK-HU-IT-NL-PL-PO-UK

NELIO 5 VET TABLETTI KISSALE: FI

\*the name will be translated into the national language

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Active substance:**

Each tablet contains:

Benazepril (as hydrochloride).....4.6 mg

(equivalent to benazepril hydrochloride ..... 5 mg)

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Tablet

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

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Cats.

**4.2 Indications for use,specifying the target species**

Cats weighing more than 2.5 kg:

- Treatment of chronic renal insufficiency.

**4.3 Contraindications**

Do not administer to pregnant or lactating females.

Do not use in case of known hypersensitivity to ACE inhibitors or to any ingredient of the product.

See also section 4.7.

**4.4 Special warnings for each target species**

None.

**4.5 Special precautions for use**

**Special precautions for use in animals**

No evidence of renal toxicity to benazepril has been observed in cats during clinical trials.

However, as is routine in cases of renal insufficiency, it is recommended to monitor plasma urea and creatinine levels.

Efficacy and safety of benazepril have not been established in cats of weight less than 2.5 kg.

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

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.

In case of accidental ingestion by children, seek medical advice immediately and show this label to the doctor.

#### **4.6 Adverse reactions (frequency and seriousness)**

Benazepril may cause mild, intermittent diarrhea in a small proportion of cats.

In cats with chronic renal insufficiency, benazepril may increase plasma creatinine concentrations at the start of therapy. This effect is related to the therapeutic effect of the product in reducing blood pressure, and therefore is not necessarily a reason to stop therapy in the absence of other signs.

Benazepril reduced erythrocyte counts in normal cats at high doses, but this effect was not observed at the recommended dose during clinical trials in cats with chronic renal insufficiency. As is routine in cases of chronic renal insufficiency, it is recommended to monitor erythrocyte counts during therapy.

Emesis, anorexia, dehydration and lethargy have been reported in rare occasions in cats.

#### **4.7 Use during pregnancy, lactation or lay**

Laboratory studies in rats have shown embryotoxic effects of Benazepril at non-maternotoxic doses (urinary system abnormalities in foetus). Benazepril administered to cats at a daily dose of 10 mg / kg for 52 weeks resulted in the reduction of ovary / oviduct weights. Safety of this product has not been tested in pregnant or lactating queens.

Do not use in pregnant or lactating females or in queens intended for breeding.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Blood pressure may be monitored during anesthesia in cats receiving benazepril.

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 a possibility.

#### **4.9 Amounts to be administered and administration route**

In cats:

Oral administration of 0.46 mg of benazepril per kg and per day, equivalent to 0.50 mg of benazepril hydrochloride per kg and per day, as one administration, whether or not with a meal, i.e one tablet per 10 kg as shown in the following table:

Cat weight (kg)	Number of tablets
2.5 - 5	0.5
5 - 10	1

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.

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.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Transient and reversible signs of hypotension may appear in case of accidental overdose. Treatment is symptomatic, involving intravenous infusion with warm isotonic saline. In cats a 10-fold overdosage daily for one year was asymptomatic.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

ATCvet code: QC09AA07

Pharmacotherapeutic group: Cardiovascular system, ACE Inhibitor, Benazepril.

#### **5.1 Pharmacodynamic properties**

Benazepril hydrochloride is a prodrug hydrolysed in vivo to benazeprilat. This active metabolite inhibits angiotensin converting enzyme (ACE), thus preventing the conversion of inactive angiotensin I into active angiotensin II. Therefore, benazeprilat inhibits all effects induced by angiotensin II, in particular, vasoconstriction of both arteries and veins and retention of sodium and water by the kidney. Benazeprilat causes long-lasting inhibition of plasma ACE, with significant inhibition persisting for 24 hours after a single dose.

In cats with renal insufficiency, benazepril reduces systemic and intraglomerular blood pressure. At the same time, it decreases glomerular basal membrane permeability. In consequence, it reduces protein loss in the urine and renal insufficiency progression.

#### **5.2 Pharmacokinetic particulars**

After oral administration, benazepril is rapidly absorbed from the gastrointestinal tract. One part of absorbed benazepril is hydrolyzed by hepatic enzymes to the active substance, benazeprilat; unchanged benazepril and hydrophilic metabolites account for the remainder. The absolute systemic bioavailability, calculated for oral benazepril versus intravenous benazepril is about 9% both in fasting and fed situations. After administration of Nelio 5 at 0.65 mg/kg in cats, peak benazeprilat concentrations (approximately 110 ng/ml) are achieved within about 1 and half hours. The apparent terminal half-life of benazeprilate was 12.5 h. Benazepril and benazeprilat are both extensively bound to plasma proteins.

Repeated administration leads to slight accumulation of benazeprilat in plasma, steady state being achieved in less than 4 days.

In cats, benazeprilat is excreted 85% via the biliary route and 15% via the urinary route. The clearance of benazeprilat is not affected in cats with decreased glomerular filtration; therefore no adjustment of the dose is required.

#### **5.3 Environmental properties**

Not applicable

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Pig liver flavour  
Yeast  
Lactose monohydrate  
Croscarmellose sodium  
Anhydrous colloidal silica  
Hydrogenated castor oil  
Microcrystalline cellulose

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf life**

*Shelf-life of the veterinary medicinal product as packaged for sale*

Blister: 21 months.

*Shelf-life of divisions of the tablets:*

72 hours

### **6.4. Special precautions for storage**

Do not store above 30°C

Store in original package.

Any part-used tablet should be returned to the opened blister and used within 3 days

### **6.5 Nature and composition of immediate packaging**

Blister complex: [PA-AI-PVC] / Aluminium heat sealed blisters with 10 tablets / blister.

Cardboard box with 1 blister of 10 tablets

Cardboard box with 2 blisters of 10 tablets

Cardboard box with 3 blisters of 10 tablets

Cardboard box with 5 blisters of 10 tablets

Cardboard box with 10 blisters of 10 tablets

Cardboard box with 20 blisters of 10 tablets

Cardboard box with 50 blisters of 10 tablets

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

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**8. MARKETING AUTHORISATION NUMBER(S)**

Vm 20749/4012

**9. DATE OF FIRST AUTHORISATION**

27/02/2009

**10 DATE OF REVISION OF THE TEXT**

27/02/2009

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

To be completed in accordance with national requirements