# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton Box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KELAPRIL 20 mg, film-coated tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Benazepril hydrochloride 20 mg
(equivalent to benazepril 18.4 mg)

## 3. PACKAGE SIZE

28 tablets
98 tablets

## 4. TARGET SPECIES

Dogs

## 5. INDICATIONS

Read the package leaflet before use.

## 6. ROUTES OF ADMINISTRATION

Oral use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of divided tablets: 2 days.

## 9. SPECIAL STORAGE PRECAUTIONS

Store below 30°C in the original package.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space inserted back into the cardboard box and used at the next administration.

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

**User warnings:** Pregnant women and women of child-bearing age should exercise caution when handling this veterinary medicinal product. 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

VetViva Richter GmbH

## 14. MARKETING AUTHORISATION NUMBERS

Vm 57446/3002

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Blister containing 14 film-coated tablets**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KELAPRIL

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg/tablet

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

VetViva Richter (logo)

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

KELAPRIL 20 mg, film-coated tablets for dogs

## 2. Composition

Each tablet contains:
**Active substance:**
Benazepril hydrochloride 20 mg
(equivalent to benazepril 18.4 mg)

**Excipients:**
Titanium dioxide (E171) 0.52 mg
Iron oxide red (E172) 0.06 mg

Reddish-pink, oval divisible film-coated tablets scored on both sides.

## 3. Target species

Dogs

## 4. Indications for use

The veterinary medicinal 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 cases 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, 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 in these species.

## 6. Special warnings

Special warnings:
The efficacy and safety of the veterinary medicinal 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 it is recommended that regular blood tests are carried out during therapy to monitor plasma creatinine, urea and blood erythrocyte counts.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
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 veterinary medicinal product has not been established in pregnant or lactating dogs.

Fertility:
The safety of the veterinary medicinal product has not been established in breeding 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, the veterinary medicinal product has been given in combination with digoxin, diuretics, pimobendan and anti-arrhythmic veterinary medicinal 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 the veterinary medicinal 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. It is recommended 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 cases of accidental overdose. Therapy should consist of intravenous infusion of warm isotonic saline.

## 7. Adverse events

**Dogs:**
Rare (1 to 10 animals / 10,000 animals treated):
Vomiting;

Fatigue

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated creatinine[1];
Incoordination

[1] In dogs with chronic kidney disease, the product may increase plasma creatinine concentrations at 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.

In double-blind clinical trials in dogs with congestive heart failure, the veterinary medicinal product was well tolerated with an incidence of adverse reactions lower than observed in placebo-treated dogs.

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.

In dogs the veterinary medicinal 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) | “Product name” 20 mg (to be completed nationally ) | |
|---|---|---|
| | Standard dose | Double dose |
| > 20 - 40 | 0.5 tablet | 1 tablet |
| > 40 - 80 | 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 (range 0.5-1.0) benazepril hydrochloride/kg body weight if judged necessary and advised by the veterinary surgeon. Always follow the dosing instructions given by the veterinary surgeon.

## 9. Advice on correct administration

None.

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30°C in the original package.
Store in a dry place.
Each time an unused half tablet is stored, it should be returned to the open blister space inserted back into the cardboard box and used at the next administration.
Shelf life of divided tablets: 2 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label 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 or household waste.

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 authorisation numbers and pack sizes

Vm 57446/3002

Blister containing 14 film-coated tablets.
Cardboard box with

- 2 blisters (28 tablets);
- 7 blisters (98 tablets).

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

September 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder, manufacturer for batch release <and contact details to report suspected adverse reactions>:
VetViva Richter GmbH,
Durisolstrasse 14,
4600 Wels,
Austria

<Local representatives <and contact details to report suspected adverse reactions>:>

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

## 17. Other information

Approved 02 January 2024