

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

PRILENAL 1 mg, tablets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One tablet contains:

**Active substance:**

Enalapril maleate 1 mg  
(Which corresponds to 0.764 mg of enalapril base)

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Tablet.

Brown spotted white round tablet.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs.

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

Treatment of mild, moderate or severe congestive heart failure, caused by mitral regurgitation or dilated cardiomyopathy, as an adjunctive therapy with diuretics (furosemide, whether associated or not with digoxin).

#### **4.3 Contraindications**

Do not use in case of hypersensitivity to enalapril or to any of the excipients.

Do not use in dogs with evidence of cardiac output failure (e.g. aortic stenosis, mitral stenosis, obstructive cardiomyopathy).

See section 4.7.

#### **4.4 Special warnings**

Pre renal azotemia generally results from hypotension due to cardio-vascular insufficiency. Substances that deplete blood volume, such as diuretics, or with a vasodilator effect, such as ACE inhibitors, may contribute to lowering systemic blood pressure.

This may create a hypotensive state or exacerbate an existing hypotensive situation and result in pre renal azotemia.

Dogs with no detectable renal disease may develop mild and transient increases in blood urea nitrogen or serum creatinine when the product is administered concomitantly with a diuretic.

The diuretic and/or enalapril dose should be reduced if clinical signs of hypotension or azotemia appear or if the blood concentration of urea nitrogen and/or creatinine increases significantly above the values observed before treatment.

Should clinical signs of overdose occur (azotemia) after the dose is increased from once daily to twice daily, the dose should be decreased to once daily.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

In case of hypokalaemia, potassium supplements can be administered concomitantly with the product. Plasma potassium should be assessed prior to treatment and periodic monitoring should be continued.

In humans, in case of renal impairment, the concomitant use of enalapril with aldosterone-antagonists can lead to hyperkalaemia. Therefore, both the renal function and plasma potassium are closely monitored in such patients. In absence of data in dogs, such recommendations should be followed in the target species.

Therapy with diuretics should be started at least 1 day prior to initiating treatment with enalapril. Renal function should be assessed prior to, and for 2-7 days after starting treatment. Periodic monitoring of renal function should be continued.

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

Wash hands after use.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

Pregnant women should take special care to avoid accidental exposure, because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

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

Hypotension and its consequences (e.g. azotemia) can occur at the start of the therapy (in less than 2 % of the treated dogs). In very rare cases, diarrhoea, vomiting, lethargy, dizziness, disorientation and in-coordination can also occur.

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

Do not use in pregnant and lactating bitches. Do not use in breeding dogs.

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

See section 4.5. special precautions for use.

Sodium chloride may decrease the hypotensive effect of enalapril.

See special warnings. Concurrent use with NSAIDs may increase the risk of renal toxicity.

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

Oral use.

0.5 mg of enalapril maleate per kg and per day (i.e. 0.38 mg of enalapril per kg and per day). Individual doses should be administered based on body weight using the most appropriate tablet size or a combination of tablets.

The dosage can be adapted according to the clinical response of the treated animal. In the absence of expected clinical response within 2 weeks following initiation of the therapy, the dose of 0.5 mg of enalapril maleate per kg per day can be administered twice a day. The increase in dose can be more rapid if the signs of heart failure require it. Dogs should be observed closely for 48 hours following initial dosing or an increase in dose.

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

Normal dogs dosed at 15 mg/kg/day for up to 1 year showed no adverse effects. This means that overdose symptoms generally appear at more than 30 times (at 0.5 mg/kg) or 15 times (at 1 mg/kg) the recommended dosage during one year.

Clinical signs reported include hypotension, azotemia, increased concentration of urea and/or creatinine. Treat symptomatically.

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

Not applicable.

# **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: ACE-inhibitors, plain.  
ATCvet code: QC09AA02.

## **5.1 Pharmacodynamic properties**

Enalapril, through its active metabolite enalaprilate, is an angiotensin-converting enzyme (ACE) inhibitor. This enzyme (peptide transferase) catalyses the conversion of angiotensin I to angiotensin II.

Angiotensin II has a vasoconstrictive activity and stimulates the secretion of aldosterone by the adrenal cortex.

The effect of enalapril, in the case of hypertension and heart failure is mainly due to the suppression of the renine-angiotensin-aldosterone system. The inhibition of ACE decreases the angiotensin II level in plasma, thereby reducing vasoconstriction and aldosterone secretion.

## **5.2 Pharmacokinetic particulars**

Plasma peaks of enalapril and its active metabolite enalaprilate are observed respectively, one hour and three hours after the oral administration of the medicinal product. The half-life of enalapril and enalaprilate are respectively 1.7 hours and 11 hours.

On average, 40% of the oral dose administered is excreted via urine and 36% in faeces during the 72 hours following administration.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Beef dry flavouring  
Maleic acid  
Lactose monohydrate  
Starch pregelatinised  
Crospovidone  
Maize starch  
Magnesium stearate

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

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

This veterinary medicinal product does not require any special storage conditions.

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

#### Material of the primary container

Complex (polyamide/Aluminium/PVC) blisters thermo sealed with an aluminium cover.

#### Pack sizes

Box containing 4 blisters of 7 tablets  
Box containing 12 blisters of 7 tablets  
Box containing 24 blisters of 7 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 product or waste materials should be disposed of in accordance with national requirements.

**7. MARKETING AUTHORISATION HOLDER**

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

**8. MARKETING AUTHORISATION NUMBER**

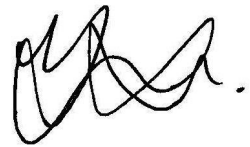
Vm 15052/4023

**9. DATE OF FIRST AUTHORISATION**

28 September 2005

**10. DATE OF REVISION OF THE TEXT**

October 2022

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

Approved : 18 October 2022