SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRILENAL 20 mg, Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substance:
Enalapril maleate 20 mg
(Which corresponds to 15.289 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
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Wooburn Green
High Wycombe
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HP10 0HH
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/4027

9. DATE OF FIRST AUTHORISATION

28 September 2005

10. DATE OF REVISION OF THE TEXT

October 2022