## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 4 blisters of 7 tablets
Box containing 12 blisters of 7 tablets
Box containing 24 blisters of 7 tablets

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilenal 1 mg, tablets
Enalapril maleate

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Enalapril maleate 1 mg
(Corresponding to 0.764 mg Enalapril base)

## 3. PHARMACEUTICAL FORM

## 4. PACKAGE SIZE

28 tablets
84 tablets
168 tablets

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

## 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 15052/4023

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

Blister of 7 tablets

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilenal 1 mg, tablets
Enalapril maleate

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Lot {number}

## 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

Prilenal 2.5 mg, tablets
Prilenal 5 mg, tablets
Prilenal 10 mg, tablets
Prilenal 20 mg, tablets
Prilenal 1 mg, tablets

## 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:
Europhartech - 1, rue Henri Matisse – BP. 23 – 63370 Lempdes - France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilenal 1 mg, tablets
Prilenal 2.5 mg, tablets
Prilenal 5 mg, tablets
Prilenal 10 mg, tablets
Prilenal 20 mg, tablets
Enalapril maleate

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

Prilenal 1 mg contains per tablet
Enalapril maleate ……..……1 mg
(corresponding to 0.764 mg of enalapril base)

Prilenal 2.5 mg contains per tablet
Enalapril maleate ……2.5 mg
(corresponding to 1.911 mg of enalapril base)

Prilenal 5 mg contains per tablet
Enalapril maleate ……..5 mg
(corresponding to 3.822 mg of enalapril base)

Prilenal 10 mg contains per tablet
Enalapril maleate ……10 mg
(corresponding to 7.645 mg of enalapril base)

Prilenal 20 mg contains per tablet
Enalapril maleate ……20 mg
(corresponding to 15.289 mg of enalapril base)

Brown spotted white round tablet.

## 4. INDICATIONS

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).

## 5. 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).

## 6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

| Animal Body weight | Product | Tablet(s) per day |
|---|---|---|
| For a dog of 1 to 2 kg | Prilenal 1 mg | 1 |
| For a dog of 2 to 4 kg | Prilenal 1 mg | 2 |
| For a dog of 4 to 8 kg | Prilenal 2.5 mg | 1 |
| For a dog of 8 to 15 kg | Prilenal 5 mg | 1 |
| For a dog of 15 to 30 kg | Prilenal 10 mg | 1 |
| For a dog of 30 to 60 kg | Prilenal 20 mg | 1 |

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister or carton after EXP. The expiry date refers to the last day of that month.

## 12. 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.

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.

Overdose:
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.

Use during pregnancy and lactation or lay:
Do not use in pregnant and lactating bitches. Do not use in breeding dogs.

Interactions:
See special precautions for use.
Sodium chloride may decrease the hypotensive effect of enalapril.
See warnings. Concurrent use with NSAIDs may increase the risk of renal toxicity.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

## 15. OTHER INFORMATION

Pack sizes

Each dosage is presented in boxes containing 28 tablets, 84 tablets or 168 tablets.

Not all pack sizes may be marketed.