# PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enacard 2.5 mg Tablets for Dogs

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Enalapril maleate

## 3. PHARMACEUTICAL FORM

Tablets

## 4. PACKAGE SIZE

4 blisters of 7 tablets each

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

For the treatment of mild, moderate and severe congestive heart failure in dogs caused by mitral regurgitation or dilated cardiomyopathy, as an adjunctive therapy with diuretics. For improved exercise tolerance and increased survival in dogs with mild, moderate or severe heart failure.

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

Dosage

The recommended dose of ENACARD in dogs is 0.5 mg/kg administered orally once daily. In the absence of a clinical response within 2 weeks the dose should be increased to a maximum of 0.5 mg/kg twice daily. Dogs must be observed closely for 48 hours following initial dosing or an increase in the dose.

## 8. WITHDRAWAL PERIOD

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

Read package leaflet for full directions and warnings before use.
Wash hands after use.

## 10. EXPIRY DATE

Expiry Date:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of unused packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4195

## 17. MANUFACTURER'S BATCH NUMBER

Batch No.**:**

## 18. FURTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enacard 2.5 mg Tablets for Dogs
(enalapril maleate USP)

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

## 3. EXPIRY DATE

Exp:

## 4. BATCH NUMBER

Batch No:

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

FOR ANIMAL TREATMENT ONLY

## 6. FURTHER INFORMATION

FOR ORAL USE

MON
TUE
WED
THU
FRI
SAT
SUN

**PACKAGE LEAFLET FOR:** Enacard Tablets for Dogs

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enacard Tablets for Dogs

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

Enalapril maleate

## 4. INDICATION(S)

ENACARD is indicated for the treatment of mild, moderate or severe congestive heart failure in dogs caused by mitral regurgitation or dilated cardiomyopathy, as an adjunctive therapy with diuretics. For improved exercise tolerance and increased survival in dogs with mild, moderate or severe congestive heart failure.

## 5. CONTRAINDICATIONS

## 6. ADVERSE REACTIONS

Pre-renal azotemia is usually a result of hypotension induced by impaired cardiovascular performance. On occasion, substances that deplete blood volume, such as diuretics, or which vasodilate, 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 minor and transient increases in blood urea nitrogen (BUN) or serum creatinine (CRT) or both, although urine analysis appears to be normal, when ENACARD is administered concomitantly with a diuretic. Renal function must therefore be monitored closely before, and 2 to 7 days after, starting the treatment with the product. The dose of diuretic and/ or ENACARD should be reduced or their use discontinued if clinical signs of hypotension or azotemia occur or the concentrations of BUN or serum CRT, or both, increase significantly over pre-treatment levels. Periodic monitoring of renal function should be continued. Should signs of overdosage occur (e.g. azotemia) after the dose is increased from once daily to twice daily, the dose should be decreased to once daily.

ENACARD has been demonstrated to be generally well tolerated. In clinical studies, the overall incidence of side effects was no greater with the product than with vehicle tablets. For the most part, side effects have been mild and transient in nature, and have not required discontinuation of therapy. Clinical signs reported include azotemia, lethargy, drowsiness, hypotension, disorientation or incoordination, but in clinical trials no significant difference in the incidence of these signs was reported between dogs receiving standard therapy and vehicle tablets and dogs receiving standard therapy and ENACARD. ENACARD at the recommended dose level has been shown to have an adequate margin of safety in dogs with heart failure. Normally healthy dogs given 15 mg/kg/day (30 times the standard recommended dose) for up to one year showed no adverse changes. The safety of the product has been thoroughly investigated in several animal species including man to assess its general toxicity.

## 7. TARGET SPECIES

Dogs

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

ENACARD should be administered orally at a recommended dose rate of 0.5 mg/kg once daily. Individual dosages should be administered on the basis of bodyweight using the appropriate tablet or combination of tablet strengths.

| Tablet Strengths | Colour |
|---|---|
| 1.0 mg | Green |
| 2.5 mg | Blue |
| 5.0 mg | Pink |
| 10.0 mg | Yellow |
| 20.0 mg | White |

In the absence of an adequate clinical response within two weeks following initiation of therapy with ENACARD, the dose should be increased, depending on the patient's response, to a maximum of 0.5 mg/kg bodyweight administered twice daily. This dose titration may be administered over a two to four week period, or more rapidly if indicated by the presence of continuing signs of congestive heart failure. Dogs should be observed closely for 48 hours following initial dosing or an increase in dose. Therapy with diuretics should be initiated at least one day prior to starting treatment with the product. Evaluation of the patient should include assessment of renal function prior to initiation of therapy and for 2 to 7 days after treatment.

## 9. ADVICE ON CORRECT ADMINISTRATION

## 10. WITHDRAWAL PERIOD(S)

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach of children.
Store blister pack in a dry place. Do not store above 25°C. Avoid transient temperatures above 50°C.

## 12. SPECIAL WARNING(S)

ENACARD is not recommended for any dog that has evidence of cardiac output failure, e.g. aortic stenosis

Special precautions for use in animals:

Whilst all clinical data were generated in conjunction with frusemide, ENACARD may be administered to dogs being treated with thiazide diuretics.

Special precautions for the person administering the veterinary medicinal product to animals:

In the case of accidental ingestion seek urgent medical attention showing the product label to the doctor or nurse. Physicians should contact a Poisons Control Centre for advice concerning cases of human consumption.

Wash hands after use.

Use in Breeding Animals:

Use of the product in pregnant bitches is not recommended. Safety in breeding dogs has not been established.

Incompatibilities:

ENACARD should not be used with potassium sparing diuretics.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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

Date of approval of the package leaflet: October 2009

## 15. OTHER INFORMATION

For animal treatment only.

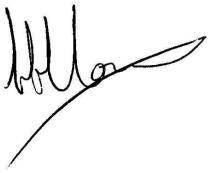
Legal Category:

POM-V

Marketing Authorisation Number:
1 mg Vm 08327/4194
2.5 mg Vm 08327/4195
5 mg Vm 08327/4196
10 mg Vm 08327/4197
20 mg Vm 08327/4198

Description:
ENACARD (enalapril maleate) is the maleate salt of enalapril, a derivative of two amino-acids, L-alanine and L-proline. Following oral administration, enalapril is rapidly absorbed and then hydrolyzed to enalaprilat, which is a highly specific, long-acting, non-sulphydryl angiotensin converting enzyme (ACE) inhibitor. The tablets are round, non-scored, and available in five colour-coded dosage strengths (1.0 mg, 2.5 mg, 5.0 mg, 10.0 mg, and 20.0 mg)

To be supplied only on veterinary prescription.



Approved 01 November 2018