**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilocard 1.25 mg tablets for dogs
Prilocard 2.5mg tablets for dogs
Prilocard 5 mg tablets for dogs

Ramipril

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains: Ramipril 1.25 mg
1 tablet contains: Ramipril 2.5 mg
1 tablet contains: Ramipril 5 mg

## 3. PHARMACEUTICAL FORM

Tablets

## 4. PACKAGE SIZE

28 tablets
140 tablets

## 5. TARGET SPECIES

Dogs

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

For oral use.
Read the package leaflet before use.

## 7. WITHDRAWAL PERIOD

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

Read the package leaflet before use.

## 9. EXPIRY DATE

EXP {month/year}

## 10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

## 11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

## 12. 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.

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

Keep out of the sight and reach of children.

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany.

## 15. MARKETING AUTHORISATION NUMBER

Vm 24745/4008

## 16. MANUFACTURER'S BATCH NUMBER

Batch {number}

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

Blister

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilocard 1.25 mg tablets for dogs
Prilocard 2.5 mg tablets for dogs
Prilocard 5 mg tablets for dogs

Ramipril

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Batch {number}

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

For animal treatment only.

**PACKAGE LEAFLET**

Prilocard 1.25 mg, 2.5 mg, 5 mg 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 holderand manufacturer for the batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany.

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilocard 1.25 mg, 2.5 mg, 5 mg tablets for dogs.

Ramipril.

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

Prilocard 1.25 mg tablets for dogs

Each tablet contains:

Active substance:
Ramipril 1.25 mg
White round biconvex tablets, imprinted with 'B' on one side of the tablet and '48' on the other.

Prilocard 2.5 mg tablets for dogs

Each tablet contains:

Active substance:
Ramipril 2.5 mg

Excipients:
Yellow ferric oxide 0.40 mg (E172)

Light yellow capsule-shaped biconvex tablets scored on one side of the tablet and imprinted with 'B' and '49' on either side of the scoring line. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Prilocard 5 mg tablets for dogs
Each tablet contains:

Active substance:
Ramipril 5 mg

Excipients:
Red ferric oxide 0.20 mg (E172)

Pink capsule-shaped biconvex tablets scored on one side of the tablet and imprinted with 'B' and '50' on either side of the scoring line.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4. INDICATION(S)

Prilocard is used for the treatment of congestive heart failure due to diseases of the heart valves. Prilocard can be used in combination with diuretic drugs and/or other heart medicine.

The veterinary surgeon may have prescribed a use or dose different from that discussed in this information. Always follow your veterinary surgeon's directions.

## 5. CONTRAINDICATIONS

Do not use Prilocard in cases of

1. allergy (hypersensitivity) to the active substance, to ACE-inhibitors or to any of the excipient(s)narrowing of the arteries
2. enlarged heart musculature with consequently impaired blood ejection
3. during pregnancy or lactation

## 6. ADVERSE REACTIONS

In rare cases – at the start of treatment or if the dose is increased – there may be a decrease in blood pressure with symptoms such as fatigue, drowsiness or movement disorders. If this occurs, discontinue the treatment and contact your veterinary surgeon.

Since high doses of diuretic drugs can cause a drop in blood pressure, avoid simultaneous administration of diuretics at the start of treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals )
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

For animal treatment only.
For oral use.

The usual dose is:
0.125 mg ramipril per kg bodyweight once daily.

This is equivalent to:
One 1.25 mg tablet per 10 kg bodyweight once daily or
One 2.5 mg tablet per 20 kg bodyweight once daily or
One 5.0 mg tablet per 40 kg bodyweight once daily.

To ensure accurate dosing, animals should be carefully weighed before calculating the dose.

Treatment should always start at the lowest recommended dose. Depending on the dog's condition and after two weeks of treatment, the dose may be increased by agreement with the veterinary surgeon to 0.25 mg ramipril per kg bodyweight

## 9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the packaging.
The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

### Special precautions for use in animals

If signs of hypotension occur, treatment with Prilocard should be suspended until fluid and electrolyte status is corrected. Treatment with Prilocard should then be continued at 50% of the original dose. In patients at risk of hypotension, it is advisable to introduce Prilocard gradually over one week (starting with half the therapeutic dose).

Kidney function should be monitored both 1-2 days before and seven days after commencement of treatment with ACE inhibitors. This also applies when the dosage of an ACE inhibitor or of a concurrently administered diuretic is increased. It is advisable to periodically monitor kidney function throughout treatment.

In patients treated concurrently with Prilocard and furosemide, the dose of diuretic can be reduced to achieve the same diuretic effect as with furosemide alone.

Do not administer potassium-sparing diuretics.

Use Prilocard tablets according to the benefit/risk assessment by the responsible veterinarian in dogs with renal and/or hepatic failure.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**
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.
Wash hands after use. In case of accidental ingestion seek immediately medical advice and show the package leaflet or the label to the physician.

People with known hypersensitivity to the active ingredient should avoid contact with the product.

**Interaction with other medicinal products and other forms of interaction**
Diuretics and a low sodium diet both potentiate the effect of ACE inhibitors by activating the renin-angiotensin-aldosterone system. High doses of diuretics and a low sodium diet should therefore be avoided during treatment with ACE inhibitors to prevent hypotension (with clinical signs such as apathy, ataxia, rarely syncope or acute renal failure).

Concomitant intake of potassium and potassium-sparing diuretics should be avoided because of the risk of hyperkalaemia.

The concomitant administration of ACE inhibitors with non-steroidal anti-inflammatory drugs (NSAIDs) leads to poor autoregulation of the glomerular blood pressure and can therefore trigger acute renal failure.

**Pregnancy & Lactation:**
No studies have been carried out to assess the use of the drug in pregnancy or lactation in bitches. ACE inhibitors have been found to be teratogenic in the second and third trimesters in other species. An angiotensin converting enzyme is known to be critical to the development of the neonatal kidney; this product should not be used in pregnancy or lactation.

**Overdose (symptoms, emergency procedures, antidotes):**
An oral dose of up to 2.5 mg ramipril per kg body weight (10 times the maximum recommended dose) was well tolerated by young, healthy dogs.

Hypotension with symptoms of apathy and ataxia may occur as symptoms of overdose.
**Incompatibilities:**
Not applicable

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

## 15. OTHER INFORMATION

Pack sizes:
Blister packs of 28 and 140 tablets.

Not all pack sizes may be marketed.

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

Approved: 09 March 2017