PACKAGE LEAFLET

PRILIUM 75 mg powder for oral solution 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
VETOQUINOL

Manufacturer for the batch release:
VETOQUINOL
MAGNY VERNOIS
F-70200 LURE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRILIUM 75 mg powder for oral solution for dogs

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Powder/vial

Imidapril hydrochloride	75 mg
Sodium benzoate (E 211)	30 mg
Excipient to	0.805 g

Solution after reconstitution

Imidapril hydrochloride	2.5 mg
Sodium benzoate(E 211)	1.0 mg
Excipient to	1 ml

4. INDICATIONS

In dogs: treatment of moderate to severe heart failure caused by mitral regurgitation or by dilated cardiomyopathy.

5. CONTRAINDICATIONS

Do not use in dogs with low blood pressure.
Do not use in dogs with acute renal insufficiency.
Do not use in dogs with congenital heart disease
Do not use in dogs hypersensitive to an ACE inhibitor
Do not use in dogs with hemodynamically relevant stenoses (aortic stenosis, mitral valve stenosis, pulmonal stenosis)
Do not use in dogs with obstructive hypertrophic cardiomyopathy

6. ADVERSE REACTIONS

Diarrhoea, hypotension and related symptoms such as fatigue, dizziness or anorexia can occur in rare cases. In such cases treatment should be discontinued until the patient's condition has returned to normal.

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

7. TARGET SPECIES

Dogs weighing over 2 kg

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

The recommended dose of imidapril is 0.25 mg/kg once a day per oral route, ie:
0.1 ml/kg of PRILIUM® 75 mg powder for oral solution for dogs weighing more than 2 kg (1ml/10kg).
The veterinary medicinal product can be administered either directly into the mouth of the animal on an empty stomach or during the meals, or on food.

Preparation of the oral solution: Remove the nipple and the stopper of the vial containing the powder and fill with tap water up to the mark (30ml) place the child proof cap and screw on tightly.
Administration: Unscrew the child proof cap, introduce the graduated syringe into the applicator, turn the assembly upside down and measure the quantity to administer using the syringe graduated in kg. Once the veterinary medicinal product has been administered, replace the child proof cap onto the vial and rinse the syringe with water. Store the vial in the fridge.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Before reconstitution: do not store above 25°C
After reconstitution: store at 2°C - 8°C (in the refrigerator)
Do not use after the expiry date stated on the carton.
Shelf-life after reconstitution: 77 days

12. SPECIAL WARNINGS

Special precautions for use in animals

The use of ACE inhibitors in dogs with hypovolaemia/dehydration can lead to acute hypotension. In such cases the fluid and electrolyte balance should be restored immediately and treatment suspended until it has been stabilised. Parameters used for monitoring renal function should be checked at the beginning of the treatment and at regular time intervals thereafter.

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

In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.
Wash hands after having administered the veterinary medicinal product. In case of contact with eyes, rinse immediately with plenty of water.
The vial must be closed using the child proof stopper before being stored in the fridge.

Use during pregnancy, lactation or lay
Laboratory studies in rats and rabbits did not produce any evidence of teratogenic, embryotoxic or maternotoxic effects, or effects on reproductive performances, when imidapril was administered at the therapeutic dose. In the absence of data, do not use in pregnant or lactating bitches or in breeding dogs.

Interaction with other medicinal products and other forms of interaction
In the clinical trial, the veterinary medicinal product has been used with furosemide and digoxin and no safety concerns were noted.
However diuretics and a low sodium diet potentiate the effect of ACE inhibitors by activating the renin-angiotensin-aldosterone system (RAAS). Diuretics used at high doses and a low sodium diet are thus not recommended during a treatment with ACE inhibitors in order to avoid hypotension with clinical signs such as apathy, ataxia, rare syncope and kidney failure. In case of joint administration with potassium retaining diuretics, potassium must be monitored because there is a risk of hyperkaliemia.

Overdose (symptoms, emergency procedures, antidotes)
Repeated oral doses up to 5 mg/kg/d of imidapril have been well tolerated in healthy dogs.
Hypotension may occur as a symptom of overdosage with signs of apathy and ataxia. The treatment is symptomatic.

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

Any unused the veterinary medicinal product or waste material should be disposed of in accordance with national requirements.
Medicines should not be disposed of via wastewater or household waste
Ask you 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

DECEMBER 2006

15. OTHER INFORMATION

For animal treatment only.

Box containing one 0.805 g white powder vial and one 2 ml graduated blue syringe. After reconstitution, the solution is limpid and colourless.

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRILIUM 75 mg powder for oral solution for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE

Imidapril hydrochloride ……..75 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Box containing one 0.805 g powder vial and one 2 ml graduated syringe

4. ROUTE(S) OF ADMINISTRATION

The veterinary medicinal product can be administered either directly into the mouth of the animal on an empty stomach or during the meals, or on food.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

7. EXPIRY DATE

EXP:
Shelf-life after reconstitution: 77 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Before reconstitution: do not store above 25°C
After reconstitution: store at 2°C - 8°C (in the refrigerator)