Prilium 150 mg

FIRST AID INSTRUCTIONS
If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

SAFETY DIRECTIONS
May irritate the eyes. Avoid contact with the eyes. Wash hands after use.

Manufactured by:
VETOQUINOL S.A.,
MAGNY VERNOIS,
70200 Lure (France)

Distributed by:
VETOQUINOL AUSTRALIA PTY LTD
Unit 302/2, 6-12 Boronia Road,
DaVinci Business Park,
Brisbane Airport, Qld, 4008

Phone: 1800 032 355
sales.australia@vetoquinol.com

APVMA N°: 58986/1205

vetoquinol

PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS
FOR ANIMAL TREATMENT ONLY

Prilium 150 mg

5 mg/mL Imidapril hydrochloride

Powder for 30mL oral solution

For treatment of moderate to severe heart failure caused by mitral regurgitation or by dilated cardiomyopathy in dogs

Net Contents: 0.880 g (containing 150 mg Imidapril hydrochloride) 2mL graduated syringe

vetoquinol

Prilium 150 mg

DISPOSAL
Dispose of empty container by wrapping in paper and putting in garbage.

STORAGE CONDITIONS
Before reconstitution: Store below 25°C (air conditioning).
After reconstitution: Store between 2°C and 8°C (refrigerate. Do not freeze).

See bottom flap for Batch and Expiry

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vetoquinol

Prilium 150 mg

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT
DIRECTIONS FOR USE
Discard unused portion within 77 days (11 weeks) after reconstitution.

Restraints: NOT TO BE USED in food-producing species of animals.

Contraindications and side effects
See leaflet

Preparation of the solution: See Leaflet

Dosage: The recommended dose of imidapril hydrochloride for dogs weighing more than 4 Kg is 0.25 mg/Kg once a day per oral route, i.e. 0.05 mL/Kg of reconstituted PRILIUM 150 mg (1mL/20Kg).

Administration: Unscrew the 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. The product can be administered either directly into the mouth of the animal on an empty stomach or during the meals, or on food. Once the product has been administered, replace the cap onto the vial and rinse the syringe with water.
Store the vial in the fridge.

vetoquinol

APPROVED NON-RLP AMENDMENT MADE

Lot:

Exp.:

Net Contents: 0.880 g

READ CARTON / ENCLOSED LEAFLET

APVMA N°: 58986/1205

Before reconstitution:
Store below 25°C (air conditioning).

After reconstitution:
Store between 2°C and 8°C (refrigerate. Do not freeze)

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

Prilium 150 mg

5 mg/mL Imidapril hydrochloride when reconstituted to 30 mL

vetoquinol

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PRILIUM 150 mg/300 mg

CONSTITUENTS

	PRILIUM 150 mg	PRILIUM 300 mg
Powder/vial		
Imidapril hydrochloride	150 mg	300 mg
Sodium benzoate Ph.Eur.	30 mg	30 mg
Excipient to	0.880 g	1.030 g
Solution after reconstitution to 30 mL		
Imidapril hydrochloride	5.0 mg	10 mg
Sodium benzoate Ph.Eur.	1.0 mg	1.0 mg
Excipient to	1mL	1mL

STATEMENT OF CLAIMS

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

PHARMACEUTICAL FORM

Powder for oral solution

Vial containing a white powder. After reconstitution the solution is limpid and colourless.

PHARMACOLOGICAL PROPERTIES

Imidapril hydrochloride is a new angiotensin-converting enzyme (ACE) inhibitor. ATC vet code: QC09AA16.

Pharmacodynamic properties:

Imidapril is a pro-drug which is hydrolysed in vivo to form an active metabolite, imidaprilat. Imidaprilat inhibits the angiotensin-converting enzyme (ACE).

This enzyme catalyses the conversion of angiotensin I to angiotensin II in the blood plasma and tissues and inhibits the breakdown of bradykinin. As angiotensin II has a potent vasoconstrictive action, while bradykinin is a vasodilator, the reduced formation of angiotensin II and the inhibition of bradykinin breakdown lead to vasodilation.

Imidapril reduces heart preload and afterload and decreases blood pressure without any compensatory increase in the heart rate.

Pharmacokinetic properties:

Following oral administration in the dog, imidapril is rapidly absorbed by the gastrointestinal tract and reaches its maximum plasma concentration within less than one hour. The half-life of imidapril is about 2 hours.

Imidapril is mainly hydrolysed in the liver and kidney to its active metabolite, imidaprilat. Maximum plasma concentrations of imidaprilat are reached within about 5 hours and decline with a half life of more than 10 hours.

The bioavailability of imidapril and imidaprilat is decreased by the joint administration of food. The protein binding of imidapril and imidaprilat is moderate (85% and 53% respectively).

After oral administration of the radio-labelled compound, about 40% of total radioactivity is excreted in urine and about 60% in the faeces.

After multiple dosing, the plasma imidaprilat concentrations are about 3 times higher after the second administration than after the first administration, but no additional increase is observed after further administrations.

DIRECTIONS FOR USE

Discard unused portion within 77 days (11 weeks) after reconstitution.

Restraints:

NOT TO BE USED in food-producing species of animals

Contraindications:

Contraindicated in dogs with low blood pressure, acute renal insufficiency, congenital heart disease or hypersensitivity to an ACE inhibitor.

Contraindicated in dogs with haemodynamically relevant stenoses (aortic stenosis, mitral valve stenosis, pulmonary stenosis).

Contraindicated in dogs with obstructive hypertrophic cardiomyopathy.

Laboratory studies on 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. However, in the absence of data, use is contraindicated in pregnant or lactating bitches or breeding dogs.

Precautions for use:

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.

Oral doses up to 5 mg/Kg of imidapril (20 times the recommended dose) 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.

Side effects:

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.

Interactions with other medicinal products and other forms of interaction:

In the clinical trial, the product has been used with furosamide 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 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 hyperkalemia.

Dosage and administration

The recommended dose of imidapril hydrochloride is 0.25 mg/Kg once a day per oral route, i.e.

0.05mL/Kg of PRILIUM 150 mg for dogs weighing more than 4 kg (1mL/20Kg)

0.025mL/Kg of PRILIUM 300 mg for dogs weighing more than 8 Kg (1mL/40Kg).

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

However studies have shown that administration on an empty stomach gave better absorption.

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 30 mL mark which is indicated by a raised ring around the body of the bottle, replace with the child proof cap and screw on tightly. Shake the bottle to ensure solution of the powder.

Administration: Unscrew the 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 product has been administered, replace the child proof cap onto the vial and rinse the syringe with water. Store the vial in the fridge.

FIRST AID INSTRUCTIONS

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SAFETY DIRECTIONS

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DISPOSAL

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STORAGE INSTRUCTIONS

Before reconstitution: Store below 25°C (air conditioning).
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APVMA No: **58985/1205; 58986/1205;**

PACK PRESENTATION

Carton containing:

Prilium 150 mg: Vial: net contents: 0.880 g (containing 150 mg Imidapril hydrochloride)
2mL graduated syringe
Leaflet

Prilium 300 mg: Vial: net contents: 1.030 g (containing 300 mg Imidapril hydrochloride)
2mL graduated syringe
Leaflet

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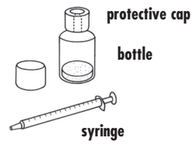
A Presentation



B Preparation of Prilium

Remove the protective cap (1) and remove the rubber stopper (2).

Pour in 30 ml of tap water up to the 30ml mark which is indicated by a raised ring around the body of the bottle as shown in the diagram.

Insert the syringe adaptor into the bottle, fit the child proof closure and screw home tightly to push the adaptor into place.

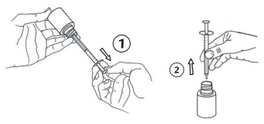
Shake the bottle to ensure solution of the powder.

Adapter in place

C Syringe filling

To remove the child proof closure press down firmly and turn at the same time.

Insert the syringe into the adaptor(1) and turn the system upside down.

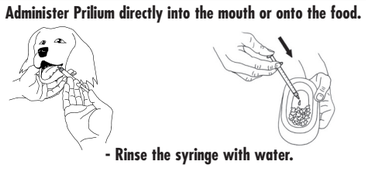


Fill the syringe to the required mark kg or ml) (1), invert the system again, and remove the syringe (2).

Reseal the container with the child proof closure, tightening the cap securely

D Administration of Prilium

Administer Prilium directly into the mouth or onto the food.



- Rinse the syringe with water.
- Place Prilium bottle back in the fridge.