

Prilium 300mg

Imidapril is a new angiotensin-converting enzyme (ACE) inhibitor.

Indications:

In dogs: treatment of heart failure of stages II, III and IV according to the NYHA classification, caused by mitral regurgitation or by dilated cardiomyopathy. The product may be combined, if necessary, with diuretics such as furosemide and/or with digoxin.

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. In addition, plasma angiotensin II induces the release of aldosterone in the renin-angiotensin system. Imidaprilat therefore reduces the secretion of aldosterone. This leads to an increase in the serum potassium concentration and a decrease in the serum sodium concentration.

So, imidapril reduces heart preload and postload, and decreases blood pressure without any compensatory increase in the heart rate arising.

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, steady-state concentrations of imidapril are reached as soon as the second day of treatment; there is neither imidaprilat nor imidapril accumulation.

Contraindications:

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.

The use of ACE inhibitors in dogs with hypovolaemia/dehydration can lead to acute hypotension. In such cases, the electrolyte balance should be restored immediately and treatment suspended until it has been stabilised.

In dogs with kidney failure, renal functions should be monitored at the beginning of therapy.

Do not use in dogs with low blood pressure.

Do not use in dogs with acute renal insufficiency.

Pregnancy and Lactation:

Laboratory studies on rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects of imidapril at the therapeutic dose.

In the absence of data, do not use in pregnant or lactating bitches.

Prilium 300mg® (cont)

Interaction with Other Medicinal Products And Other Forms Of Interaction

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 hyperkalaemia.

Overdose (Symptoms, Emergency Procedures, Antidotes)

Repeated oral doses of up to 5 mg/kg/day of imidapril have been well tolerated in healthy young dogs.

Hypotension may occur as a symptom of overdose with signs of apathy and ataxia. The treatment is symptomatic.

Special Precautions to Be Taken By the Person Administering the Product to Animals

In case of accidental ingestion, seek medical advice immediately.

Wash hands after having administered the product. In case of contact with eyes, rinse immediately with plenty of water.

Specific Precautions For Storage

Before reconstitution: do not store above 25°C

After reconstitution: store between 2 and 8°C

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, place the childproof cap and screw on tightly.

Administration:

Unscrew the childproof 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 childproof cap onto the vial and rinse the syringe with water. Store the vial in the fridge.

Dosage:

The recommended dose of imidapril is 0.25mg/kg once a day per oral route, i.e. 0.025ml/kg of Prilium 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 of the active ingredient.

Presentation:

Primary packaging:

- Amber glass vial of type II
- Halobutyl stopper
- Polypropylene graduated syringe
- Polyethylene syringe applicator
- Polyethylene childproof cap

Sales presentation(s): Box containing one 0.805g powder vial and one 2ml-graduated syringe.

Registered pursuant to the ACVM Act 1997,

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RESTRICTED VETERINARY MEDICINE

Prilium 300mg

For Animal Treatment Only



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