Ceva Animal Health Ltd

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Prilactone Next® 10mg, 50mg and 100mg chewable tablets for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Diuretics

Active ingredient: Spironolactone

Product: Prilactone Next® 10mg, 50mg and 100mg chewable tablets for dogs

Product index: Prilactone Next

Incorporating:

Qualitative and quantitative composition

One tablet contains

Active substance:

Spironolactone.....10, 50, or 100 mg

Excipients:

For a full list of excipients, see Pharmaceutical particulars.

Pharmaceutical form

Chewable tablets.

10 mg tablet: Oblong shaped scored beige tablet. The tablet can be divided into two equal parts.

50 mg and 100 mg tablet: Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

Clinical particulars

Target species

Dogs.

Indications for use

For use in combination with standard therapy (including diuretic support, where necessary) for the treatment of congestive heart failure caused by degenerative mitral valve disease in dogs.

Contraindications

Do not use in animals used for or intended for use in breeding.

Do not use in dogs suffering from hypoadrenocorticism, hyperkalaemia or hyponatraemia.

Do not administer spironolactone in conjunction with NSAIDs to dogs with renal insufficiency.

Do not use in cases of hypersensitivity to spironolactone or any of the excipients.

See Use during pregnancy, lactation or lay.

Special warnings for each target species

None.

Special precautions for use

Special precautions for use in animals

Kidney function and plasma potassium levels should be evaluated before initiating combined treatment with spironolactone and ACE inhibitors. Unlike in humans, an increased incidence of hyperkalaemia was not observed in clinical trials performed in dogs with this combination. However, in dogs with renal impairment, regular monitoring of renal function and plasma potassium levels is recommended as there may be an increased risk of hyperkalaemia.

Dogs treated concomitantly with spironolactone and NSAIDs should be correctly hydrated. Monitoring of their renal function and plasma potassium levels is recommended before initiation and during treatment with combined therapy (see Contraindications).

As spironolactone has an antiandrogenic effect, it is not recommended to administer the product to growing dogs.

As spironolactone undergoes extensive hepatic biotransformation, care should be taken when using the product to treat dogs with hepatic dysfunction.

The chewable tablets are flavoured. In order to avoid accidental ingestion, store these tablets out of the reach of animals.

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

The product may cause skin sensitization. Persons known to be allergic to spironolactone or other components of the final formulation should not handle this product.

Handle this product with great care to avoid unnecessary exposure, taking all recommended precautions.

Wash hands after use.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse reactions (frequency and seriousness)

Very common (>1 animal / 10 animals treated):

Common (1 to 10 animals / 100 animals treated):

1in entire male dogs, reversible

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Spironolactone had developmental toxicity in laboratory animals.

The safety of the product has not been assessed in pregnant and lactating bitches.

Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

In clinical studies, the product was co-administered with ACE-inhibitors, furosemide and pimobendan without evidence of associated adverse reactions.

Spironolactone decreases digoxin elimination and hence raises digoxin plasma concentration. As the therapeutic index for digoxin is very narrow, it is advisable to monitor closely dogs receiving both digoxin and spironolactone.

The administration of either deoxycorticosterone or NSAIDs with spironolactone may lead to a moderate reduction of the natriuretic effects (reduction of urinary sodium excretion) of spironolactone.

Concomitant administration of spironolactone with ACE-inhibitors and other potassium-sparing drugs (as angiotensin receptor blockers, ß-blockers, calcium channels blockers, etc.) may potentially lead to hyperkalaemia (see Special precautions for use in animals).

Spironolactone may cause both induction and inhibition of cytochrome P450 enzymes and could therefore affect the metabolism of other drugs utilizing these metabolic pathways.

Amounts to be administered and administration route

Prilactone Next 10 mg dosing:

2 mg of spironolactone per kg of body weight once daily, i.e. 1 tablet per 5 kg of body weight, by oral route. The product should be administered with meal.

Dog weight (kg)	**Prilactone Next 10mg** **Number of tablets per day**
> 1 to 2.5	½
> 2.5 to 5	1
> 5 to 7.5	1½
> 7.5 to 10	2

Prilactone Next 50 mg dosing:

2 mg of spironolactone per kg of body weight once daily, i.e. 1 tablet per 25 kg of body weight, by oral route. The product should be administered with meal.

Dog weight (kg)	**Prilactone Next 50mg** **Number of tablets per day**
> 3 to 6	¼
> 6 to 12.5	½
> 12.5 to 18	¾
> 18 to 25	1
> 25 to 31	1¼
> 31 to 37	1½
> 37 to 43	1¾
> 43 to 50	2

Prilactone Next 100 mg dosing:

2 mg of spironolactone per kg of body weight once daily, i.e. 1 tablet per 50 kg of body weight, by oral route. The product should be administered with meal.

Dog weight (kg)	**Prilactone Next 100mg**

	Number of tablets per day
> 6 to 12.5	¼
> 12.5 to 25	½
> 25 to 37.5	¾
> 37.5 to 50	1
> 50 to 62.5	1¼
> 62.5 to 75	1½
> 75 to 87	1¾

The tablets are flavoured. If the dog does not accept the tablet from hand or bowl, then the tablets may be mixed with a small amount of food offered prior to the main meal, or administered directly into the mouth after feeding.

Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves.

Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of up to 5 times the recommended dose (10 mg/kg) to healthy dogs, dose-dependent adverse effects were noted, see Adverse Reactions.

In case of an accidental massive ingestion by a dog, there is no specific antidote or treatment. It is therefore recommended to induce vomiting, lavage the stomach (depending on risk assessment) and monitor electrolytes. Symptomatic treatment, e.g., fluid therapy, should be provided.

Withdrawal period(s)

Not applicable

Pharmacological particulars

Pharmacotherapeutic group: Aldosterone antagonist. ATCvet code: QC03DA01

Pharmacodynamic properties

Spironolactone and its active metabolites (including 7α-thiomethyl-spironolactone and canrenone) act as specific antagonists of aldosterone, and exert their effects by binding competitively to the mineralocorticoid receptor located in the kidneys, heart and blood vessels.

Spironolactone is a natriuretic drug (historically described as a soft diuretic). In the kidney, spironolactone inhibits the aldosterone-induced sodium retention leading to increase in sodium and

subsequently water excretion, and potassium retention. The renal effects of spironolactone and its metabolites lead to a decrease in extracellular volume and consequently in a decrease of cardiac preload and left atrial pressure. The result is an improvement in heart function.

In the cardiovascular system, spironolactone prevents the detrimental effects of aldosterone. Although the precise mechanism of action is not yet clearly defined, aldosterone promotes myocardial fibrosis, myocardial and vascular remodelling and endothelial dysfunction.

In experimental models in dogs, it was shown that long term therapy with an aldosterone antagonist prevents progressive left ventricle dysfunction and attenuates left ventricle remodelling in dogs with chronic heart failure.

When used in combination with ACE-inhibitors, spironolactone may counteract the effects of "aldosterone escape".

A slight increase in aldosterone blood levels may be observed in animals on treatment. This is thought to be due to activation of feedback mechanisms without adverse clinical consequence. There may be a dose related hypertrophy of the adrenal zona glomerulosa at high dose rates.

Pharmacokinetic particulars

The pharmacokinetics of spironolactone are based on its metabolites, as the parent compound is rapidly metabolised.

Absorption

In dogs, oral bioavailability of spironolactone as measured by canrenone AUCs was 83% relative to the iv route. It has been shown that feeding significantly increases the oral bioavailability of all measured metabolites resulting from dosing dogs with spironolactone. After multiple oral doses of 2 mg spironolactone per kg for 5 consecutive days, steady-state conditions are reached by day 3 and only a slight accumulation of canrenone is observed. After oral administration of spironolactone in dogs at 2 mg/kg, a mean Cmax of 41 ng/mL is achieved for the primary metabolites, canrenone, after 4 hours.

Distribution

The mean apparent volume of distribution during elimination phase after oral dosing in dogs was 41 L/kg for canrenone.

The mean residence time of the metabolites ranges from 11 hours.

The protein binding is about 90%.

Metabolism

Spironolactone is rapidly and completely metabolised by the liver into its active metabolites, canrenone, 7α-thiomethyl-spironolactone and 6β-hydroxy-7α-thiomethyl-spironolactone, which are the primary metabolites in the dog.

Elimination

Spironolactone is mainly excreted via its metabolites. Plasma clearance of canrenone is 3 L/h/kg for canrenone, in dogs. After oral administration of radiolabelled spironolactone to the dog, 66% of the dose is recovered in faeces and 12% in the urine. 74% of the dose is excreted within 48 hours.

Pharmaceutical particulars

List of excipients

Artificial chicken flavour, Yeast, Crospovidone type A, Sodium lauryl sulfate, Maltodextrine, Magnesium stearate, Silica, colloidal anhydrous, Silicified microcrystalline cellulose, Lactose monohydrate.

Major incompatibilities

None

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 24 hours for 10 mg tablets; 72 hours for 50 mg & 100 mg tablets

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

Store in the original package

Any part-used tablet should be returned to the opened blister and used within 24 hours for 10 mg; 72 hours for 50 mg & 100 mg tablets

Nature and composition of immediate packaging

(PA-AL-PVC - aluminium heat sealed) containing 10 tablets per blister (10 mg & 50 mg) or 8 tablets per blister (100 mg)

10 mg tablets: Cardboard box of 10 tablets containing 1 blister of 10 tablets; Cardboard box of 20 tablets containing 2 blisters of 10 tablets; Cardboard box of 30 tablets containing 3 blisters of 10 tablets; Cardboard box of 60 tablets containing 6 blisters of 10 tablets; Cardboard box of 100 tablets containing 10 blisters of 10 tablets; Cardbaord box containing 180 tablets containing 18 blisters of 10 tablets.

50 mg tablets: Cardboard box of 10 tablets containing 1 blister of 10 tablets; Cardboard box of 20 tablets containing 2 blisters of 10 tablets; Cardboard box of 30 tablets containing 3 blisters of 10 tablets; Cardboard box of 100 tablets containing 10 blisters of 10 tablets; Cardboard box of 180 tablets containing 18 blisters of 10 tablets.

100 mg tablets: Cardboard box of 8 tablets containing 1 blister of 8 tablets; Cardboard box of 16 tablets containing 2 blisters of 8 tablets; cardboard box of 24 tablets containing 3 blisters of 8 tablets; Cardboard box of 56 tablets containing 7 blisters of 8 tablets; Cardboard box of 80 tablets containing 10 blisters of 8 tablets.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Number

10 mg:

GB Vm 14966/5088

NI Vm 14966/3087

50 mg:

GB Vm 14966/5089

NI Vm 14966/3088

100 mg:

GB Vm 14966/5090

NI Vm 14966/3089

Significant changes

Date of the first authorisation or date of renewal

8 August 2012

Date of revision of the text

November 2025

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

NOAH Compendium

GTIN description: Prilactone Next 10 mg 3x10T

GTIN:3411112265633

GTIN description: Prilactone Next 50 mg 3x10T

GTIN:3411112264940

GTIN description: Prilactone Next 100 mg 3x8T

GTIN:03411113065942