Veterinary Medicinal Product

PRILACTONE NEXT 50 MG CHEWABLE TABLETS FOR DOGS

PART I B

A - LABELLING

Pharmaceutical Form

Chewable Tablet

Veterinary Medicinal product

PRILACTONE NEXT 50 MG CHEWABLE TABLETS FOR DOGS

PART IB

A – LABELLING – "OUTER PACKAGE"

Pharmaceutical form

Chewable Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg chewable tablets for dogs

Spironolactone

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains
Active substance:
Spironolactone .....50 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
100 tablets
180 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Store in the original package.
For shelf life of divided tablets: see package leaflet.

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

Disposal: read the package leaflet before use.

13. 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4117

17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal product

PRILACTONE NEXT 50 MG CHEWABLE TABLETS FOR DOGS

PART IB

A – LABELLING – BLISTER

Pharmaceutical form

Chewable Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg chewable tablets for dogs

Spironolactone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Veterinary Medicinal product

PRILACTONE NEXT 50 MG CHEWABLE TABLETS FOR DOGS

PART IB

B – PACKAGE LEAFLET

Pharmaceutical form

Chewable Tablet

PACKAGE LEAFLET

PRILACTONE NEXT 50 MG CHEWABLE 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 holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer for the batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg chewable tablets for dogs

Spironolactone

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

One tablet contains
Active substance:
Spironolactone .....50 mg
Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

4. INDICATION(S)

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.

5. 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 section “Pregnancy and lactation”.

6. ADVERSE REACTIONS

A reversible prostatic atrophy is often observed in entire male dogs. Vomiting and diarrhoea may commonly occur.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

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

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 50 mg Number of tablets per day
> 3.0 to 6.0	¼
> 6.0 to 12.5	½
> 12.5 to 18.0	¾
> 18.0 to 25.0	1
> 25.0 to 31.0	1 ¼
> 31.0 to 37.0	1 ½
> 37.0 to 43.0	1 ¾
> 43.0 to 50.0	2

9. ADVICE ON CORRECT ADMINISTRATION

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.

As feeding significantly increases the oral bioavailability of spironolactone it is recommended to administer the product during the meal.
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.

10. WITHDRAWAL PERIOD (S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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 72 hours

12. SPECIAL WARNING(S)

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 section “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.

Pregnancy and lactation
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 section “Special precautions for use”).
Spironolactone may cause both induction and inhibition of cytochrome P450 enzymes and could therefore affect the metabolism of other drugs utilizing these metabolic pathways.

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 section “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.

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

Medicines should not be disposed of via wastewater. 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

October 2022

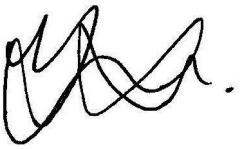
15. OTHER INFORMATION

Pack sizes:
Cardboard box with 10 tablets

Cardboard box with 20 tablets
Cardboard box with 30 tablets
Cardboard box with 100 tablets
Cardboard box with 180 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: 12 October 2022