PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg chewable tablets for dogs
Spironolactone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:

Active substance:

Spironolactone.....50 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
100 tablets
180 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {xx/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBER

Vm 14966/5089

15. BATCH NUMBER

Batch:

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary Medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg chewable tablets for dogs
Spironolactone

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Batch:

4. EXPIRY DATE

EXP {xx/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 50 mg Chewable Tablets for Dogs

2. COMPOSITION

One tablet contains:
Active substance:
Spironolactone 50.0 mg

Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

3. TARGET SPECIES

Dogs

4. 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.

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. SPECIAL WARNINGS

Special precautions for safe use in the target species
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.

Special precautions for the protection of the environment

Not applicable

Other precautions

Not applicable

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

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.

Major incompatibilities

Not applicable

7. ADVERSE EVENTS

Dogs:

Very common (>1 animal / 10 animals treated):	Prostatic atrophy[1]
Common (1 to 10 animals / 100 animals treated):	Vomiting, Diarrhoea

[1]in entire male dogs, reversible

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of the leaflet, or via your national system details:

Website:https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTES 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 PERIODS

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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
These measures should help to protect the environment.
Ask you veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5089

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing Authorisation Holder:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication Zone Autoroutière
53950 LOUVERNE FRANCE

POM-V Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall
Approved: 05 November 2025