ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next 100 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains
Active substance:
Spironolactone .....100 mg

3. PACKAGE SIZE

8 tablets
16 tablets
24 tablets
56 tablets
80 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral administration

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}
Once divided, use within 72 hours

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package

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

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/3030

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prilactone Next

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

100 mg of spironolactone

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Prilactone Next 100 mg chewable tablets for dogs

2. Composition

One tablet contains
Active substance:
Spironolactone .....100 mg
Clover-shaped scored beige chewable 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 sensitisation. 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:
The safety of the product has not been assessed in pregnant and lactating bitches.
Laboratory studies in laboratory animals have shown evidence of developmental toxicity.
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.

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 the package leaflet, or you think that the medicine has not worked, please contact, in the first instance, you veterinarian. You can also report any adverse events to the marketing authorization 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

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

Dog weight (kg)	Prilactone Next 100 mg Number of tablets per day
> 6.0 to 12.5	¼
> 12.5 to 25.0	½
> 25.0 to 37.5	¾
> 37.5 to 50.0	1
> 50.0 to 62.5	1 ¼

> 62.5 to 75.0	1 ½
> 75.0 to 87.0	1 ¾

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 temperature storage conditions.
Store in the original package.
Any part-used tablet should be returned to the opened blister and used within 72 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 15052/3030

Pack sizes:
Cardboard box with 8 tablets
Cardboard box with 16tablets
Cardboard box with 24 tablets
Cardboard box with 56 tablets
Cardboard box with 80 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 and 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: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer for the batch release:

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

17. Other information

Gavin Hall

Approved: 27 December 2024