ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosoral 10 mg tablets for cats and dogs / pictograms

furosemide

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains:
Active substance:
Furosemide 10 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets
250 tablets
500 tablets
1000 tablets
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Any unused tablet portion should be returned to the open blister and used within 3 days

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

Disposal: read package leaflet

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

Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4020

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium-PVDC/PVC blisters or Aluminium-PVDC/PE/PVC

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosoral 10 mg tablets for cats and dogs
furosemide

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot.

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Furosoral 10 mg tablets for cats and 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:

Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Artesan Pharma GmbH & Co. KG
Wendlandstraße 1, 29439 Lüchow
Germany

or

Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

or

Genera Inc.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosoral 10 mg tablets for cats and dogs / Furosoral vet 10 mg tablets for cats and dogs
Furosemide

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

One tablet contains:
Active substance:
Furosemide 10 mg

White to yellow-white round and convex tablet with a cross-shaped break line on one side and embossing 10 on the other side. Tablets can be divided into two or four equal parts.

4. INDICATION(S)

Treatment of hydrothorax, hydropericardium, ascites and oedema, particularly associated with cardiac insufficiency and renal dysfunction.

5. CONTRAINDICATIONS

Do not use in animals suffering from hypovolaemia, hypotension or dehydration.
Do not use in cases of renal failure with anuria.
Do not use in cases of electrolyte deficiency.
Do not use in cases of known hypersensitivity to furosemide, sulphonamides or any of the excipients.
Do not use in acute glomerular nephritis.
Do not use in patients that have received excessive doses of cardiac glycosides.
Do not use in combination with other loop diuretics.

6. ADVERSE REACTIONS

In rare (more than 1 but less than 10 animals in 10,000 animals treated) cases, soft faeces may occur. This sign is transient and mild and does not necessitate the withdrawal of the treatment.

Due to the diuretic action of furosemide, in rare cases there may be hemoconcentration and impairment of the circulation. In cases of prolonged treatment electrolyte deficiency (including hypokalemia, hyponatremia) and dehydration may rarely occur.

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.

7. TARGET SPECIES

Cats and dogs.

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

For oral administration.
The recommended starting dose is 2.5- 5 mg furosemide per kg bodyweight per day, corresponding to ½ - 1 tablet per 2 kg bodyweight. In severe oedematous or refractory cases, the daily dose may initially be doubled. For maintenance, daily dosage should be adapted to the lowest effective dose by the veterinarian depending on the clinical response of the dog/cat to the therapy.

9. ADVICE ON CORRECT ADMINISTRATION

If treatment is administered last thing at night this may result in inconvenient diuresis overnight.

10. WITHDRAWAL PERIOD

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.
Any unused tablet portion should be returned to the open blister and used within 3 days
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for each target species:
Therapeutic efficacy may be impaired by increased intake of drinking water. Where the animal's condition permits, water intake should be restricted to physiologically normal levels during treatment.

Special precautions for use in animals:
Furosemide should be used with caution in the case of pre-existing electrolyte and/or water imbalance, impaired hepatic function (may precipitate hepatic coma) and diabetes mellitus.
In case of prolonged treatment, hydration status and serum electrolytes should be monitored frequently.
1-2 days before and after commencement with diuretics and ACE inhibitors renal function and hydration status should be monitored.
Furosemide should be used with caution in patients with nephrotic syndrome.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Furosemide has possible genotoxic properties and there is evidence of carcinogenicity in mice. Although there is inadequate evidence relating to these effects in humans, skin contact with or accidental ingestion of the product should be avoided. Wear impervious gloves during handling and administration of the product and wash hands thoroughly afterwards.
Each time an unused part-tablet is stored until next use, it should be returned to the open blister space and inserted back into the cardboard box. The product should be stored safely, out of the sight and reach of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to furosemide and other ingredients in the product should avoid contact with the veterinary medicinal product. Do not handle this product if you know you are sensitive to sulphonamides as hypersensitivity to sulphonamides may lead to hypersensitivity to furosemide. 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. Wash hands after use.

Interaction with other medicinal products and other forms of interaction
In cats, do not use furosemide with ototoxic antibiotics.
Concurrent use with drugs affecting electrolyte balance (corticosteroids, other diuretics, amphotericin B, cardiac glycosides) requires careful monitoring.
Concomitant use with aminoglycosides or cephalosporins may increase the risk of nephrotoxicity.
Furosemide may increase the risk of sulfonamide cross-reactivity.
Furosemide may alter insulin requirements in diabetic animals.
Furosemide may reduce the excretion of NSAIDs.
The dose regimen may need to be reduced for long term treatment in combination with ACE inhibitors, depending upon the animal's response to therapy.

Overdose (symptoms, emergency procedures, antidotes)
Doses higher than recommended may cause transitory deafness, electrolyte and water balance problems CNS effects (lethargy, coma, seizures) and cardiovascular effects (hypotension, heart rhythm disorders, collapse), especially in old and weakened animals. Treatment is symptomatic.

Pregnancy and lactation
Laboratory studies have shown evidence of teratogenic effects.
The safety of the product has not been established during pregnancy or lactation.
However furosemide is excreted into milk.
In pregnant and lactating animals, use only according to the benefit/risk assessment by the responsible veterinarian.
A deleterious effect on lactation is to be expected, particularly if drinking water is restricted.

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

Medicines should not be disposed of via wastewater or household waste.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2024

15. OTHER INFORMATION

Cardboard box containing 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25, 50 or 100 blisters of 10 tablets each, respectively corresponding to 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 250, 500, or 1000 tablets per box.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.