

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Furosemal 40 mg tablets for cats and dogs / pictograms  
furosemide

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 tablet contains:  
**Active substance:**  
Furosemide 40 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 41821/4021

**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 40 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:**

**Furosoal 40 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**

Furosoal 40 mg tablets for cats and dogs / Furosoal vet 40 mg tablets for cats and dogs  
Furosemide

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

One tablet contains:

**Active substance:**  
Furosemide 40 mg

White to yellow-white round and convex tablet with a cross-shaped break line on one 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 8 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**

May 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.

Approved 18 May 2024

*Gavin Hall*