SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosoral 40 mg tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

Active substance:
Furosemide 40 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
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. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

In rare (more than 1 but less than 10 animals in 10,000 animals tested) 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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Diuretics, furosemide
ATC Vet Code: QC03CA01

5.1 Pharmacodynamic properties

Furosemide is a derivate of sulfamoyl antranil acid and is a fast acting diuretic in humans and animals. It inhibits resorption of sodium and chloride ions in the kidneys mainly in the ascending Loop of Henle, but also in the proximal and distal renal tubules resulting in an increased water excretion. An isotonic or slightly hypotonic urine with unchanged or slightly acidic pH is produced. Excretion of potassium ions is only enhanced at very high doses.
Furosemide has no effect on carbonic anhydrase.

5.2 Pharmacokinetic particulars

Furosemide is absorbed rapidly mostly in the stomach and upper small intestine Maximum concentrations were measured at 1.1 hour after oral administration in cats and at 0.8 hours in dogs. After a mean oral dose of 5.2 mg/kg, Cmax in cats was 8.8 µg/ml. After a mean oral dose of 1.9 mg/kg, Cmax in dogs was 0.9 µg/ml.
Metabolism of furosemide is very limited. It is predominantly excreted via the kidneys, whilst the rest is excreted via the gastrointestinal tract. Elimination half-life was 3.7 hours in cats and 2.4 hours in dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Cellulose, microcrystalline
Povidone
Crospovidone
Talc
Pregelatinized starch
Silicon dioxide
Colloidal anhydrous silica
Long chain partial glyceride

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of divided tablets: 3 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Any unused tablet portion should be returned to the open blister.

6.5 Nature and composition of immediate packaging

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25, 50, or 100 Aluminium-PVDC/PVC blisters with 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4021

9. DATE OF FIRST AUTHORISATION

21 January 2015

10. DATE OF REVISION OF THE TEXT

August 2019

Approved: 01 August 2019